

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Norfolk Division

IN RE:

ZETIA (EZETIMIBE)
ANTITRUST LITIGATION

CIVIL ACTION NO.
2:18md2836

TRANSCRIPT OF PROCEEDINGS

Norfolk, Virginia

April 14, 2023

BEFORE: THE HONORABLE REBECCA BEACH SMITH
United States District Judge

1 APPEARANCES:

2 GLASSER & GLASSER PLC

By: William H. Monroe, Jr.

3 And

HAGENS BERMAN SOBOL SHAPIRO, LLP

4 By: Thomas M. Sobol

Kristen A. Johnson

5 Erin C. Burns

Kristen A. Johnson

6 Rachel Downey

And

7 KESSLER TOPAZ MELTZER & CHECK LLP

By: Terence S. Ziegler

8 And

9 BERGER & MONTAGUE PC

By: Ellen Noteware

And

10 FARUQI & FARUQI, LLP

By: Bradley J. Demuth

11 Joseph T. Lukens

Neill W. Clark

12 And

RADICE LAW FIRM, P.C.

13 By: John D. Radice

14 Counsel for FWK Holdings, LLC, Cesar Castillo,
Inc., Rochester Drug Cooperative, Inc.

15 KENNY NACHWALTER, P.A.

16 By: Scott E. Perwin

Anna T. Neill

17 Lauren C. Ravkind

And

18 WOLCOTT RIVERS GATES P.C.

By: John Sawyer

19 And

HANGLEY ARONCHICK SEGAL PUDLIN & SCHILLER

20 By: Eric L. Bloom

Barry L. Refsin

21 Counsel for Walgreen Co., The Kroger Co.,
22 Albertsons Companies, Inc., HEB Grocery
Company, L.P., and Rite Aid Corp.

1 APPEARANCES CONTINUED:

2 FURNISS DAVIS RASHKIND & SAUNDERS PC

3 By: James A Cales, III

4 And

5 MOTLEY RICE LLC

6 By: Michael M. Buchman

7 And

8 MILLER LAW LLC

9 By: Marvin A. Miller

10 Matthew E. Van Tine

11 Kathleen Boychuck

12 Counsel for City of Providence, Rhode Island,

13 Painters District Council No. 30, The

14 Uniformed Firefighters' Association of Greater

15 New York Security Benefit Fund, The Retired

16 Firefighters' Security Benefit Fund

17 KAUFMAN & CANOLES, P.C.

18 By: Stephen E. Noona

19 And

20 GIBSON DUNN & CRUTCHER LLP

21 By: Samuel G. Liversidge

22 Christopher D. Dusseault

23 Meredith S. Simons

24 Jillian London

25 Courtney L. Spears

Chris Whittaker

And

GOLDMAN ISMAIL TOMASELLI BREENAN & BAUM LLP

By: Jennifer L. Greenblatt

Tarek Ismail

Counsel for Defendants Merck & Co., Inc.;

Merck Sharp & Dohme Corp., now known as Merck

Sharp & Dohme LLC, Schering-Plough Corp.;

Schering Corp. and MSP Singapore Co., LLC

1 APPEARANCES CONTINUED:

2 KIRKLAND & ELLIS, LLP

3 By: Kevin M. Neylan, Jr.

4 Devora W. Allon

5 Patrick J. Gallagher

6 James R.P. Hileman

7 And

8 WOODS ROGERS VANDEVENTER BLACK

9 By: Richard H. Ottinger

10 Jennifer L. Eaton

11 Counsel for Glenmark Pharmaceuticals, Ltd.,

12 and Glenmark Pharmaceuticals Inc., USA

13 incorrectly identified as Glenmark Generics,

14 Inc., USA

1 (Hearing commenced at 1:03 p.m.)

2 THE CLERK: In Re: Zetia Antitrust Litigation,
3 Case Number 2:18md2836.

4 Are the parties ready to proceed?

5 MR. MONROE: Your Honor, Bill Monroe representing
6 the direct purchasers. We are ready to proceed.

7 THE COURT: The direct purchasers are ready to
8 proceed?

9 MR. MONROE: Yes. Thank you.

10 MR. CALES: Your Honor, Jim Cales on behalf of the
11 end payor purchasers. We are ready to proceed.

12 MR. SAWYER: Your Honor, John Sawyer on behalf of
13 the retail plaintiffs Giant Eagle and Burlington plaintiffs.
14 We are ready to proceed.

15 THE COURT: Good afternoon, Counsel.

16 MR. SAWYER: Thank you, Your Honor.

17 MR. CALES: Thank you, Your Honor.

18 MR. NOONA: Good afternoon, Your Honor. Stephen
19 Noona on behalf of Merck. We are ready to proceed.

20 MR. OTTINGER: Good afternoon, Your Honor. Richard
21 Ottinger on behalf of the Glenmark defendants. We are ready
22 to proceed.

23 THE COURT: Good afternoon, Counsel, as well as all
24 of the other counsel who are present today.

25 We will start the hearing, I'll just make a couple

1 of brief remarks, and then we will proceed into some
2 substance. The purpose of our hearing today is to hear
3 evidence to enable the Court to decide whether the *Mylan*
4 case and its result is admissible. That's a very simple
5 statement, but to what point the evidence is admissible
6 pursuant to motion *in limine* number 19, which I'm just going
7 to say is plaintiffs' motion in this case.

8 Judge Miller did issue a ruling in this matter and,
9 "Conclude that evidence related to the re-issued Zetia
10 patent and its assertion against *Mylan* is relevant to
11 disputed issues of fact in this case, including plaintiffs'
12 alternative settlement causation theory and defendants'
13 defense that the settlement had procompetitive effects."
14 That's from his memorandum order, which is 2000 at 2.

15 Judge Miller also found that the *Mylan* evidence,
16 "Poses a serious risk of misleading and confusing the jury."
17 That's in the same place.

18 Ultimately, Judge Miller ruled that the *Mylan*
19 evidence was admissible but that the Court would need to
20 carefully scrutinize how it should be used during trial.
21 Again, that is from his opinion.

22 Subsequent to that, the defendants responded to the
23 Court. The Court issued a notice order. That was notice
24 order number 1. I believe it was issued on April 23rd. I
25 have it here in the packet. But, in any event, it was

1 issued, and in that order the Court indicated it would take
2 this issue under advisement and would give you a ruling
3 before the evidence was presented, that you would not be
4 able to mention it in opening statements. So that was what
5 resulted in this defendants' response to the notice order
6 restrictions on the discussion of *Mylan* evidence and
7 requested this pretrial hearing under Federal Rule of
8 Evidence 104.

9 I would note that if you read 104, basically the
10 first two reasons for having a Rule 104 evidence hearing are
11 criminal. They only pertain to a criminal case. There is a
12 caveat there which says, "Or justice so requires." I'm
13 going to be asking questions about why "justice so
14 requires."

15 So at this juncture, I want to start the hearing.
16 Mr. Noona, you can come forward to the podium.

17 MR. NOONA: Yes, ma'am.

18 THE COURT: Mr. Noona, you are local counsel for
19 the Merck defendants, and you are the individual who signed
20 this motion; is that correct?

21 MR. NOONA: It is. I am.

22 THE COURT: Consequently, the Court holds you
23 responsible for this motion, as you know. Under our local
24 rules, the Court at any time, and I say this, and I want
25 counsel to pay close attention to this statement by the

1 Court. If you're not familiar with the rules, you need to
2 go read that rule because that's who the Court looks to, is
3 local counsel. Local counsel is required to sign pleadings,
4 and the Court can hold local counsel responsible for that
5 filing and responsible for any part of the case.

6 So all the local counsel at any time, on the
7 Court's direction, have to be willing to step in and take
8 over. That means examining witnesses, that means arguing,
9 and I will set the ground rules before trial, but I'm just
10 telling you this in advance. There is going to be notices
11 and warnings if conduct is not under control, and I'll
12 explain it in great detail before we start the trial.

13 Basically, you get one warning, you get two
14 warnings, and on the third warning, you're at a flagrant
15 one. That flagrant one will then prohibit you from
16 continuing with whatever examination you were doing, and
17 local counsel will take over for that examination or that
18 witness. You can still come back into trial for
19 examination.

20 After that, there will be warning one, warning two,
21 flagrant two. If you get a flagrant two, then what is going
22 to occur is you may certainly be at trial, you may
23 participate with your counsel, but you may not examine
24 witnesses or cross-examine witnesses or argue, because this
25 is going to be an orderly process. I have looked at the

1 transcripts, and it's been very disappointing to the Court
2 to see the lack of civility that has occurred at least in
3 pretrial hearings.

4 As I've said in my notice order, you will not talk
5 over each other, you will not talk over the Court, and you
6 will not talk over witnesses. There are ways to conduct
7 yourself in a trial, no matter how large it is, no matter
8 how much money is involved, and no matter how zealous you
9 are for your clients.

10 So I just add that on now, but I wanted to call
11 Mr. Noona up to the podium so I could ask him about this
12 pleading he filed because I've got questions about it.

13 Do you have it in front of you, Mr. Noona?

14 MR. NOONA: Your Honor, I'll get it.

15 THE COURT: This is not directed at you, Mr. Noona.
16 I know that you filed the pleadings and you signed the
17 pleadings, so this is not a statement in any way directed at
18 you either personally or as local counsel for Merck in this
19 matter. This is something directed at both sides.

20 The Court, in going through these pleadings, has
21 become weary of the misconception of the Court's orders, and
22 this applies equally to both sides. I'm going to go through
23 this, and I'm going to ask you what's the purpose of this
24 statement, because you signed the pleading.

25 On Page 1, it says, "It will be extremely

1 prejudicial to defendants if plaintiffs are allowed to
2 present all of their arguments, both pre- and
3 post-settlement, many of which the *Mylan* evidence is
4 directly relevant to rebut. While defendants are barred
5 from telling the jury about the *Mylan* evidence, such a
6 one-sided presentation of the claims and defenses in this
7 case will give plaintiff an unfair advantage right out of
8 the starting gate.

9 "Defendants expect that plaintiffs will tell the
10 jury in their opening statements that prior to the
11 settlement of Glenmark, Merck would have thought its patent
12 was weak and vulnerable to Glenmark's inventorship argument;
13 i.e., the claim that Dr. Afonso should have been named as an
14 inventor on Merck's Ezetimibe patent because Afonso was the
15 first to conceive the operative method used to make
16 compounds 4E and 4F, and it was afraid to go to trial on
17 that issue. Yet, the Court's notice order, defendants
18 cannot respond in their opening by pointing to the fact that
19 Merck actually took issue with Afonso, whether Afonso was
20 the first to conceive the operative method of making
21 compounds 4E and 4F."

22 Now, what leads you to believe and make a statement
23 that the Court is going to allow the plaintiffs to present
24 evidence post-settlement? The Court's order said no
25 evidence. It said your evidence, opening statements need to

1 be restricted to the settlement and pre-settlement, no
2 post-settlement evidence. I could point you to ten places,
3 and I will continue to. Why is that implication in a
4 pleading on the record?

5 MR. NOONA: I think that the plaintiffs' theory is
6 that we settled the case because we thought we had a weak
7 patent and that we paid the generic in order not to have to
8 go forward with that case. That's all pre-settlement -- I
9 mean, pre-Mylan case at the settlement time.

10 I think the arguments that are made here throughout
11 the lawsuit have been strung together, that they certainly
12 are going to argue that we settled this case in order to
13 avoid losing our patent. There is a dispute over whether
14 there is a consistent argument concerning causation and
15 damages, and there is two different theories for that. We
16 had a whole hearing on that, Your Honor.

17 But they have never parsed that argument and made
18 the argument that solely based on the information that was
19 in front of the plaintiffs at that exact moment -- or Merck
20 at that moment, did they think it was weak. They have
21 always, and their expert who testified about this, has
22 always said that they settled because they thought the
23 patent was weak and that part of that was an invalidity
24 challenge. The only challenge that was left was this
25 inventorship. And the theory in all of the hearings has

1 been that they did that to buy time to fix things. Whether
2 they get into what they did or they didn't, they are still
3 going to make that argument.

4 I know Mr. Sobol. He's said this many times in all
5 of the hearings. They are going to say that we settled the
6 case in order to buy off a weak patent.

7 THE COURT: Excuse me for a minute. I'm not saying
8 he may not ultimately say that. Maybe you did, because you
9 had the patent re-issued. The patent that you settled on is
10 not the patent that you won on.

11 MR. NOONA: I'm happy to explain that.

12 THE COURT: No. I don't want that explained. I'm
13 not so much talking about the merits at this point, which we
14 will get into, but the implication that the Court would
15 allow one side to present evidence -- or it's not evidence.
16 That's the whole point of an opening statement. It is not
17 evidence. It is not argument. Opening statements
18 oftentimes are restricted until courts have made rulings.

19 The implication of this order was that the Court
20 was somehow going to allow plaintiffs' counsel to talk about
21 all of their evidence post-settlement and not the
22 defendants', and I don't know where in the order you come up
23 with that. It's like you're saying, we don't trust the
24 plaintiffs' counsel, they're not going to obey your order.
25 If they didn't, I would call them down without hesitation

1 during an opening statement to say, you know the Court's
2 order does not allow you to go into that in opening
3 statement. It will be decided at the appropriate time
4 whether you can use it as evidence.

5 MR. NOONA: But with respect, Your Honor, if I
6 stand in front of the jury as the plaintiff and I say,
7 "Merck was afraid to go to trial, they were absolutely
8 afraid to go to trial, and what they did was they bought off
9 that lawsuit."

10 THE COURT: Well, isn't that a good argument?

11 MR. NOONA: They are going to make that argument.

12 THE COURT: Well, they were afraid to go to trial,
13 weren't they?

14 MR. NOONA: I don't believe so.

15 THE COURT: Then why won't you have your Merck
16 attorneys in here? You're complaining about these
17 percentages that Dr. Hrubiec has put forward, and yet you
18 have claimed attorney-client privilege and will not explain.
19 Who can explain Merck's position better than their
20 attorneys? You're not waiving your attorney-client. You
21 want to open the door for all of this evidence that you want
22 to put in, but you're not willing to put your attorneys on.
23 So my assessment is, and it may be the jury's assessment is,
24 that you probably had legal advice. Big companies don't
25 settle cases without legal advice.

1 You all have refused to allow the Merck attorneys
2 at that time to come before this Court, and the jury is
3 what's important. Somebody has got to make this clear to
4 the jury, and this is as clear as mud in some areas. As far
5 as I'm concerned, if you're not willing to have your
6 attorneys come in and say, no, we didn't settle it for that
7 reason. I've read all this. I've been reading the
8 transcripts and keeping up with things. So why?

9 MR. NOONA: It is my understanding, Your Honor,
10 that Merck made a decision, which is their right, not to
11 waive attorney-client privilege. That causes the issue that
12 you are talking about, but that does not mean that Merck
13 will not come to trial with fulsome evidence that it did not
14 settle this case from an objective point of view because it
15 was afraid of losing its patent.

16 They have an expert, Mr. Armitage, who will come
17 forward and who will explain in great detail, as he did in
18 his report, that based on several objective facts, that
19 clearly they did not settle this case for fear of losing at
20 a 65 percent chance that Mr. Hrubiec says, that they had a
21 good case, that, in fact, this patent was a patent that was
22 the type of patent that had never been broken on a generic
23 type of challenge.

24 The re-issue that you mentioned earlier, one thing,
25 Your Honor --

1 THE COURT: That's going to come in, I can tell
2 you. I am not going to allow a jury to be confused and
3 misled.

4 MR. NOONA: Let me tell you something.

5 THE COURT: Wait just a minute.

6 MR. NOONA: Yes, ma'am. Yes, ma'am.

7 THE COURT: I won't give you warning one.

8 But that is going to come in. You're not going to
9 stand in here and say, well, we won the *Mylan* litigation.
10 There are so many differences, and once you start down that
11 road and into that rabbit hole, it's all going to come out,
12 and at some point the Court is going to have to explain the
13 purpose of the evidence and what exactly occurred, because
14 what you all did was you went in and got it re-issued. So
15 if you were so convinced that that patent was so good, why
16 did you get it re-issued before you proceeded with the *Mylan*
17 case?

18 MR. NOONA: Your Honor, one of the fundamental
19 problems in this case is having a clear understanding of and
20 not broad-brushing the re-issue of the patent. When I go
21 back to the Patent Office, and I ask to re-issue a patent, I
22 can go in and ask that certain claims be changed, not the
23 whole patent, and, in fact, what was at issue in Glenmark
24 was not changed, and very importantly, from a patent
25 perspective, you cannot get rid of invalidity. You cannot

1 expunge the invalidity if it happened in the original
2 patent.

3 That is why, when you look at the decision that
4 Linares made, Judge Linares had to look at both the
5 re-issued patent and the original patent because the
6 inventorship issue is live. The Patent and Trademark Office
7 has to look at it, the Judge has to look at it. You can't
8 just bypass it because you've re-issued the patent.

9 Now, in particular, the issue of inventorship was
10 live in both of these cases, and the issue of whether or not
11 Mr. Afonso was an inventor was at issue in these two cases.
12 Were there other differences? Perhaps. And certainly they
13 did go back into the office and change part of the patent.
14 That was what they do. You have to do that.

15 THE COURT: Excuse me, but I want to say something.
16 First of all, I'm familiar with patent law.

17 MR. NOONA: Yes, ma'am.

18 THE COURT: I have been hearing patent cases for
19 over 30 years, or about 30 years now. Actually, over. I
20 know about patents and getting them re-issued, so I don't
21 need that explained.

22 I can't imagine that that kind of explanation is
23 going to go before a jury in an antitrust case. This is an
24 antitrust case. It's not a patent case. Yes, it revolves
25 around certain patents, but this jury is not going to be

1 diverted by patent law. This is an antitrust case. The
2 patents ultimately were different in the Glenmark case and
3 that settlement and in the *Mylan* case.

4 That's why patent lawyers do what they do. When
5 they see a weakness, yeah, go in and get it re-issued and
6 get that aspect of it changed. So I think we should end our
7 discussion of patent law because patent law is not going to
8 go before this jury. They are simply going to be told that
9 there are certain procedures that can be taken to change and
10 correct things in patents. That's what patent law is a lot
11 about and *Markman* hearings.

12 In any event, I was just concerned, Mr. Noona, by
13 this continuous in here that somehow the Court was going to
14 allow this one-sided presentation. I mean, on Page 4 you've
15 got an argument that said that there was an implication
16 through this whole matter that all of this would go in
17 somehow by plaintiffs, and the Court never said that.

18 If they even open the door in their opening
19 statements, if I rule in their favor, and I don't know how
20 I'm going to rule, that's why I took it under advisement, if
21 they open that door in their opening statement, the door is
22 opened, and then I'll open it wide up. As soon as you open
23 a door, you can't close it, so you have to be very careful.
24 I'm not saying both, but I have noticed in this, if you are
25 given an inch, you try to open it to a foot. I'm going to

1 tell you that you open the door, and it just was replete
2 throughout this. Like Page 6, the conclusion, Mr. Noona. I
3 know you signed this. You signed it as local counsel. "The
4 claim is based on post-settlement evidence, and it would be
5 profoundly unfair to allow plaintiffs to make this claim
6 without allowing Merck to explain that despite the re-issue,
7 it, in fact, went to trial in *Mylan* on the same inventorship
8 claim that was at issue in Glenmark."

9 That didn't affect the opening statement because I
10 said that neither party could mention all of this. I didn't
11 say that only the defendants were precluded. I just said
12 that no one would issue it, no one would mention it in
13 opening statement, and that includes what's in here.

14 Finally, and we will end this because I'm not going
15 to hold you to it, I'm not trying to argue with you. I'm
16 just trying to make it clear.

17 MR. NOONA: Your Honor, I am before you, and I am
18 ready, willing, and able to argue this. I appreciate your
19 comments. Nothing in this paper was meant to suggest that
20 the Court was going to do anything wrong. We were just
21 trying to explain that we didn't want to be in front of a
22 jury and not be able to tell our side of the story.

23 THE COURT: Well, that would not happen because you
24 said in here if they were allowed to present their evidence
25 during the first week of trial, that would be inherently

1 unfair, and if they called any witnesses until I've made a
2 ruling on this, then they've opened it up, and I'm letting
3 everybody know that right now. You open the door, and I
4 will hold you to it. You all are experienced civil
5 attorneys, and you know the rules, and you know what opening
6 the door means. So I do have to consider the probative
7 value of all of this *vis-à-vis* the confusion to the jury,
8 and that's an important matter.

9 Finally, I would say on Page 7, you say,
10 "Plaintiffs' claim. By settling the litigation with
11 Glenmark, Merck believed that it bought itself exclusivity
12 and eliminated generic competition until December 2016."
13 Well, that's what this case is about. That's exactly what
14 the case is about. Then you say that the claim is
15 demonstrably false, and the jury might not agree with that.
16 So, I mean, I know that's argument, and I accept that is
17 argument, and I know that this is an issue, and I know it's
18 an important issue.

19 So I just don't want it to be left that somehow
20 that the Court opened the door for the plaintiffs and closed
21 it for the defendants. So I don't understand. I know it's
22 argument, but I just would tell you that there was some of
23 this that was just over-the-top argument, as far as I was
24 concerned. I know it would have been better to focus on
25 this as an important issue, and it would help both sides for

1 it to be decided before trial, and I'm well aware of that.

2 MR. NOONA: We appreciate the guidance, Your Honor.

3 THE COURT: The final thing I would say, and this
4 is something we are going to hear about today, but you're
5 making Dr. Hrubiec's testimony of the 65/75 percent chance
6 of winning, that patent counsel would have advised Merck.

7 Well, you can rebut that simply by bringing on your
8 attorneys. What did they advise? You can waive an
9 attorney-client privilege. So that's something that you can
10 waive, and you don't waive it, and that raises red flags.
11 I'm just telling you, I don't know how that's going to be
12 handled, but you're supposed to present the best evidence on
13 an issue. So the best evidence, in my opinion, would be
14 whoever was advising at that time, but I'm not there yet.

15 MR. NOONA: Thank you, Your Honor.

16 THE COURT: Mr. Noona, I thank you. I know how
17 diligent you are, and I appreciate your rising to the
18 occasion.

19 MR. NOONA: I am more than happy, always to stand
20 up, maybe not as prepared as you would have liked me to be,
21 but I do check and read everything that I sign, Your Honor.

22 THE COURT: I know you do, and I don't doubt the
23 competence of any of the local counsel nor any competence of
24 counsel. It's local counsel that I look to.

25 MR. NOONA: Thank you, Your Honor.

1 THE COURT: Thank you.

2 I'm going to call upon plaintiffs to argue their
3 position first since it's their motion *in limine*.

4 Mr. Sobol, I understand you are going to argue.
5 Mr. Sobol?

6 MR. SOBOL: Yes.

7 THE COURT: You are going to argue that?

8 MR. SOBOL: Yes, Your Honor. Good afternoon. May
9 it please the Court. Tom Sobol, Hagens Berman Sobol
10 Shapiro, for the direct purchasers and arguing for all the
11 plaintiffs.

12 What I would like to first do, Your Honor, is we
13 have some handouts, and if I could approach to have those
14 handed up, please.

15 Have to get it to the important person.

16 THE COURT: Were you a law clerk at one point, Mr.
17 Sobol?

18 MR. SOBOL: I was, Your Honor, to the former Chief
19 Justice Allan Hale in his retirement year up in
20 Massachusetts.

21 THE COURT: So you, like all other law clerks,
22 thought you knew more than the judge?

23 MR. SOBOL: I was one of the rare exceptions. He
24 was quite something. But I learned an awful lot. I hope
25 that your clerk learns as much as I learned in my year.

1 So, Your Honor, first I just want to put in context
2 what the arguable relevance is of the *Mylan* patent merits to
3 the case so that we know what the legal issue is under which
4 these factual issues are being addressed.

5 If I understand it, there are two possible legal
6 hooks, if you will, under which the probabilities of the
7 *Mylan* litigation are arguably relevant. One is assessing
8 the anticompetitive effects of the reverse payoff, reverse
9 payment in exchange for the avoidance of a competitively
10 balanced agreed entry date. That's one of their relevance
11 issues. But, however, when we are looking at the
12 anticompetitive effects of any agreement, we evaluate it at
13 the time of the agreement.

14 This is stated in our briefs, but if you go to our
15 slide 3, please, you will see that -- and these are cases
16 that were cited in Judge Miller and I think in some of your
17 rulings in this case. But the competitive effects of an
18 agreement or of a challenged restraint are assessed at the
19 time that the agreement is entered into.

20 Then if you go to the next slide, which is slide 4,
21 these cases on slide 4 and slide 5 also indicate that what
22 you do when you are looking at an anticompetitive restraint,
23 here, again, the anticompetitive restraint being a reverse
24 payment to avoid the potential for earlier risk under a
25 competitively balanced agreed entry date, avoiding that risk

1 is you assess it at the time of the agreement. Why does
2 that make sense? Because we are trying to hold antitrust,
3 potential antitrust wrongdoers accountable for their actions
4 at the time of their agreement rather than letting them have
5 it be assessed later on down the road to determine whether
6 or not what kind of effects it ended up having. That's at
7 least how you look at the violation issue.

8 In this case, if I understand it correctly, the
9 *Mylan* case, the *Mylan* situation is only relevant, if it's
10 relevant at all -- and the plaintiffs don't think it is --
11 the *Mylan* situation is only relevant to the agreement to the
12 extent that the victory in the *Mylan* case would have allowed
13 Glenmark onto the market earlier. That's the only way that
14 it ends up being relevant. But our position on that is,
15 that's talking about why the acceleration clauses in the
16 agreement are procompetitive. It is not explaining why
17 you've done a reverse payment to avoid an earlier entry
18 date.

19 The second legal reason, and probably far more
20 germane to this case, is that when looking at and trying to
21 determine a competitively balanced agreed entry date, I
22 think Your Honor can see that I'm using the language from
23 your summary judgment decision, which I thought it was,
24 frankly, very precise in trying to define the kind of risks
25 that was avoided, allegedly avoided in this case. So a

1 competitively balanced agreed entry date is determined by
2 the facts as existed at the time of the agreement, May 2010.

3 And one looks to -- one would have expected that
4 Glenmark and Merck's lawyers, although they haven't
5 testified, would have looked at the facts that had been
6 developed during the course of that two-year or three-year
7 litigation to be able to assess where they were going to go
8 at that point in time.

9 The defendants then say, well, we would like to
10 look at what the result was in *Mylan* two years later as
11 predictive of what people would have known in May of 2010.
12 Obviously, our first position on that is that can't be the
13 case. No one knew in May of 2010, at the time that Glenmark
14 and Merck settled that case, what would happen in the Merck
15 versus *Mylan* case. You could not know what was going to
16 happen then. You make predictions in May of 2010, like a
17 forecaster forecasts the weather in May of 2010, and the
18 legitimacy or lack of legitimacy of your forecast in May of
19 2010 is based upon the facts and circumstances and the
20 science, or here the law, as it existed at that time, and
21 you are held accountable for the reasonableness of that
22 forecast. It can't be the case that you look at something
23 that happened much later on down the road.

24 Now, assuming then that a Court were to entertain
25 then. Well, okay, but we are still going to look at what

1 happened with the *Mylan* case, because it turns out that the
2 forecast was only 30 percent rain, but it did rain, you
3 know, later on down the road, so now we're going to look at
4 the fact that it rained, and now you're going to try to
5 figure out was the forecast wrong or not, even though the
6 forecast was probably solid at the time.

7 So what happened after Glenmark settled? And I'll
8 do this as very quickly and as in a summary fashion as I
9 can. Four weeks after Glenmark settled, the chief person at
10 Schering, Merck's company they bought, the chief patent
11 person at Schering swore under oath to the patent office
12 that the '721 patent was invalid in whole or in part by
13 reason of that fact that that patent claimed more than the
14 patentee was entitled to, swore to that under oath
15 unequivocally.

16 Now, there are other parts of the submission that
17 was made that day four weeks after the Glenmark case
18 settled, when seeking the re-issue, where the patentee,
19 where Merck tried to waffle or hedge its bets by saying,
20 well, allegedly this was said or we might have done that,
21 but the oath was unequivocal, our patent, in whole or in
22 part, is invalid.

23 Subsequently, when the patent office re-issued that
24 patent under the re-issue statute, the patent office, as a
25 matter of law, had to also have concluded that the '721

1 patent was invalid, in whole or in part, in order to allow
2 re-issue. And then once Merck was willing to surrender,
3 which is required under the law under '721 -- under the
4 patent re-issue statute, they had to surrender the '721 and
5 get a brand-new patent.

6 Now, we don't know why Merck sought re-issue. They
7 haven't put witnesses up to testify about why. So we can
8 only have what objectively one would reasonably infer.
9 What's the first thing one would reasonably infer? You're
10 trying to improve your chances. You're trying to improve
11 your patent. There can't be any other explanation for it.
12 You have left in the patent, that's now being re-issued,
13 bullet claims to Ezetimibe, the active ingredient of Zetia,
14 and the only explanation that has to be that you went
15 through this process of re-issue, which was in no way
16 guaranteed, and brushed it so clearly, right in the
17 aftermath of Glenmark, to be able to improve your chances.

18 Now, why is that even relevant, in part, to this
19 motion is this. There is no one who can be able to educate
20 the jury about what -- how much those chances were improved
21 by the re-issue. How would the jury even begin to
22 understand that on this rabbit hole or this sideshow, and
23 none of even the experts for either side have said, well, a
24 re-issue, when you do this under the circumstances, it
25 increases your chances X amount. So even though Mylan won

1 in the end, you've got to discount that by X amount, because
2 nobody knows. But, in any event, they re-issued it.

3 Then what's the next thing that they do? So when
4 Merck was before the *Mylan* -- in the Glenmark case, excuse
5 me, Merck took the position that a gentleman by the name of
6 Mr. Rosenblum had conceived of these two compounds, 4E and
7 4F. That was their position. They had him -- that he was
8 the one who had conceived it.

9 In that case, in Glenmark also, Mr. Rosenblum said
10 that he had a method by which he could make these two
11 compounds, and there was a dispute as to whether he could
12 make this, these two compounds. So Merck also had another
13 gentleman, a man by the name of Mr. Brisbois, a scientist,
14 who came in and said, I looked at Mr. Rosenblum's method,
15 and I can recreate it, and that was their position in
16 Glenmark.

17 After getting the re-issue, Merck, in their
18 findings of fact, and we have this in the slides, changed
19 their position, and they said, no, the earlier inventors of
20 these beta-lactam compounds, and Mr. Burnett and then
21 Mr. Clader, they conceived of these two compounds. They, in
22 the course of their more fundamental research and prior
23 patents, they are the ones who came up with these two
24 compounds, and not only that, but it was they who had the
25 ways to make these two compounds.

1 And Merck even pointed out to the Court in the
2 *Mylan* case that Mr. Rosenblum, and this other gentleman,
3 Mr. Afonso, but Mr. Rosenblum hadn't even gotten onto the
4 project until Mr. Burnett and Mr. Clader had conceived of
5 these two compounds and hadn't disclosed methods to make
6 them. So it was different as to who made the key compounds
7 that were being disputed. It changes.

8 Again, now, how is that going to be explained to
9 our antitrust jury about that kind of a difference, about
10 what happens when you change your theory about who made the
11 compounds? But another difference is this. In the Glenmark
12 case, Glenmark was pursuing three different challenges to
13 the patent. In *Mylan*, *Mylan* only chose one. How do we
14 balance those?

15 In the Glenmark case, Glenmark was only saying that
16 this gentleman thought he was the inventor, Mr. Afonso.
17 They were only saying Mr. Afonso made compounds 4E and 4F,
18 he was the inventor of 4E and 4F.

19 But in the *Mylan* case, *Mylan* decided to say
20 that Afonso, not only did he make 4E and 4F, he also made
21 Ezetimibe. He was an inventor of Ezetimibe itself, the
22 fundamental difference.

23 So, and then there is one other thing, too, the
24 kind of thing that would be presented to the jury.

25 THE COURT: You are talking about now in your case

1 in chief?

2 MR. SOBOL: Well, if this comes up, if the
3 defendants are entitled to say, we are going to put on the
4 *Mylan* results, right, in our case, then I think it's
5 appropriate for me to start out at the gate and say, well,
6 I'm not going to let the jury to think that we are hiding
7 from this issue. I want to be able to put on my own
8 evidence directly to say, you know why Glenmark was a weak
9 case? Because now I'm going to show you why they did all
10 this stuff, you know, colloquially, but they did all these
11 things in a later case in order to improve their chances,
12 that from which you, jury, you can infer that they must have
13 had a weak case to begin with.

14 I don't want to have to be going down any of this.
15 I do think the whole thing is a distraction, but my point is
16 it's like your allusion to a door, Your Honor. If the *Mylan*
17 result door gets opened, it gets opened all the way, and
18 then the plaintiffs take the position that we are going to
19 thrust all of this in front of the jury because we want to
20 show the jury not that this case inevitably would have lost
21 but that they were doing things to clean up their act.

22 THE COURT: Well, if you were so concerned with the
23 admissibility of the *Mylan* evidence at trial, why did you
24 not bring it up at summary judgment or an earlier time, and
25 you waited until the 11th hour to file the motion *in limine*?

1 MR. SOBOL: So it was not clear to us early on what
2 our position should be with respect to this evidence at all.
3 And what we thought was more important was to fight each
4 fight as it came along, meaning there were two times that it
5 came up: One was at *Daubert* against Dr. Hrubiec, Robert
6 Hrubiec, and the other time was at summary judgment.

7 We indicated that we didn't think it was relevant,
8 but, you're right, our primary argument was it does not get
9 rid of the case as a whole, and we thought that that was the
10 appropriate way to proceed. And when it did come time to
11 file our motions *in limine*, these were timely filed months
12 ago.

13 THE COURT: Well, let me ask you this question. Is
14 your position that all this *Mylan* evidence should be
15 excluded or just which post-dates the Merck-Glenmark?

16 MR. SOBOL: Just what post-dates the Merck-Glenmark
17 settlement, Your Honor.

18 THE COURT: Okay. Do you propose any type of a
19 limiting instruction being given to the jury about all of
20 the post-settlement evidence? Have you come up with
21 anything? Because, certainly, we are not going to
22 re-litigate the *Mylan* case here.

23 MR. SOBOL: Right. So if I understand what the
24 Court is asking, our position with respect to the
25 post-Merck-Glenmark settlement *Mylan* evidence is that all of

1 that should come out, and if all that evidence comes out,
2 I'm not aware of something that would end up being before
3 the jury for which we would have to give them a limiting
4 instruction.

5 Now, I do want to -- just so that I'm completely
6 transparent -- I want to be clear, there are other kinds of
7 things that happened in this case, not about *Mylan*. There
8 are other things that happened in this case after the
9 settlement, obviously, which would be coming in, but that
10 doesn't have anything to do with *Mylan*.

11 THE COURT: I understand. I'm saying this
12 basically to both parties, if it comes in, I'm talking about
13 the post-settlement, it's got to be, if the Court let's it
14 in, some type of a limiting instruction or something that
15 would have to go to the jury to put into context why this
16 evidence in another case in another patent is coming in
17 before them.

18 I'll mention some things later at the conclusion of
19 the hearing, a couple of suggestions I have, but in any
20 event, I just wanted you all to be thinking of, if the
21 evidence does come in, some type of limiting instruction.

22 Go ahead. I basically just wanted to mention those
23 while you were talking about it. It sounds like all the
24 *Mylan* evidence, and I don't know why you all can't agree
25 about some stipulation that, okay, we all know that the

1 patent was changed. I don't understand. Both sides, and
2 I'm going to mention this in the end, are inviting error.
3 As far as I'm concerned, if it is let in, that you would be
4 wise to come up with some kind of stipulation or agreement.
5 I mean, there are certain things, facts are facts, and the
6 fact is you went in and you got the patent re-issued. The
7 fact is, you can maybe talk about the similarities, but
8 ultimately you are talking about different patents,
9 different cases. I mean, there are certain things that are
10 fact that could be in a stipulation that would reduce the
11 confusion to the jury.

12 MR. SOBOL: Sure.

13 THE COURT: Anyway, you were giving me such a
14 history of the *Mylan* litigation, and I read a lot about it.
15 I certainly hope all of that wouldn't come in for a jury.
16 Wouldn't propose for the whole scenario of what occurred
17 from the Glenmark settlement to the conclusion of the *Mylan*
18 litigation, but go ahead.

19 MR. SOBOL: Thank you, Your Honor. Yes, so I think
20 a large part of our position, our point in terms of that,
21 going through the whole background, is that -- and I've made
22 my way about halfway, maybe a little bit more than halfway
23 through the differences between the Glenmark case and the
24 *Mylan* case, is that in order for the jury, if the jury gets
25 any suggestion that the *Mylan* case prevailed, they will need

1 to have before them evidence about each of these various
2 changes and when they happened, and they won't be told why
3 the defendant did it, but they would have to make estimates
4 about why they did it, and our point then is you end up in
5 this situation where you are just so far down the road that
6 you end up in a truly situation where you're very much
7 confusing the jury.

8 Let me go through a couple of the final points and
9 I'll move on with the argument. So in the Glenmark case,
10 you recall that I indicated that the Merck position there
11 was that this Mr. Rosenblum had been the inventor. He had
12 tried to make the compounds 4E and 4F. There was a dispute
13 whether he could. And then Merck came up with a scientist
14 by the name of Mr. Brisbois who said that he could do and
15 tried to do it. Then there was a dispute about whether he
16 could do it.

17 That same evidence was also presented in the *Mylan*
18 case. We have a similarity there. However, when the *Mylan*
19 court in New Jersey made its decision, it observed that this
20 Brisbois, this Mr. Brisbois had testified but did not rely
21 upon that evidence at all in its decision.

22 So you have the reality that the *Mylan* court
23 actually rejected one of the arguments that had been made in
24 Glenmark, adding some more confusion to more differences.

25 Well, we also know about what the *Mylan* court did,

1 was that the *Mylan* court said, you know, regarding this 4E
2 and 4F, I agree with you, Merck, on your new position as to
3 who conceived it. It's Mr. Burnett and Mr. Clader, right,
4 and that's who they said who had first conceived it, and
5 they said that those gentlemen had had methods that were in
6 place before. So you have all of these various differences
7 between the two cases that would end up with very
8 significant juror confusion.

9 There is another issue that overlaps this, and this
10 deals with a little bit, I think, Your Honor, of -- let me
11 take a step back. I have given a lot of thought also to
12 Judge Miller's decision on this issue and how would a court
13 go about trying to police appropriately, you know, shifting
14 sands on what it is that people do here with respect to
15 this.

16 There are some subsidiary facts. I'm not sure if
17 the parties could agree with what they are with the
18 stipulations, and, you're right, frankly, we have not been
19 very successful in reaching an awful lot of stipulations of
20 fact in this case, but what I will say is this. There are
21 many issues also of characterizations of patent law, patent
22 principles, and characterizations like it's the same patent.
23 Well, it's not the same patent. They are saying it's the
24 same law, but it's not the same law as it was in *Therasense*.

25 They say it was the same issue of inventorship, but

1 that's misleading because it is not really the same issue of
2 inventorship if you are saying in one case the one group
3 conceived of it, and then you're saying in the other case
4 somebody else conceived of it, it's not the same issue.

5 And if you tell the jury, well, it's the same issue
6 of inventorship, you have an expert who is -- their expert
7 is as adamant and 100 percent characteristic about these
8 issues as counsel's advocacy about it's the same this, it's
9 the same that. Now the plaintiffs are in the position of
10 saying, well, it's not really the same way, it's not the
11 same way this. And, frankly, at some point, the plaintiffs
12 would call upon the Court, with all respect, to say, well,
13 wait a second, Your Honor, they're mischaracterizing an
14 issue of law. And this Court knows -- or we would
15 advocate -- because I'm not going to suggest what the Court
16 knows, but advocate that this Court can't let either the
17 counsel or their witness mischaracterize comparison of these
18 two cases if it is incorrect as a matter of law.

19 THE COURT: Well, I will tell you in my opinion
20 it's not the same patent. Now, how you qualify that, I'm
21 not speaking to that, but it is not the same. Ultimately,
22 it is not the same patent. I know it, and all of you all
23 know it. So that would have to be qualified for the jury
24 that it was changed. It's not the same patent as at the
25 time the Glenmark settlement went forward, which has

1 resulted in all of this antitrust litigation.

2 Excuse me for a minute.

3 Go ahead.

4 MR. SOBOL: Finally, Your Honor, I want to end up
5 on another point of law. If you can turn to our slide 29,
6 please.

7 This issue, as you can imagine, Your Honor, in some
8 of these reverse payment cases, this issue or issues like
9 this arise from time to time. In our briefing, we have
10 cited this case. We also replicate it here. In the *Namenda*
11 court, there was a similar kind of issue that arose
12 regarding a confidential memorandum, and Judge McMahon was
13 of the opinion to exclude that evidence because it did not
14 come to light to the parties until after they settled the
15 Paragraph 4 litigation. And so, again, you have this issue
16 where if you've got things that are cropping up after the
17 parties settle, then it ought not be influencing the jury's
18 analysis in terms of assessing the anticompetitive
19 agreement.

20 Also, in the *Apotex* case, our slide 31, we think
21 that Judge Goldberg did a very good way of navigating these
22 waters. In that case what Judge Goldberg did was realized
23 that a later invalidation of the patent would be unduly
24 prejudicial to the defendants, even though the defendants'
25 patent was found to be procured by inequitable conduct. On

1 the issue of violation, he said as a matter of law it should
2 not come in, so he bifurcated this trial and made sure it
3 did not come in that for that reason.

4 THE COURT: As an aside, so you all know, I have
5 not only reviewed the *Apotex* opinion, but I've read all the
6 jury instructions.

7 MR. SOBOL: Okay. Thank you.

8 THE COURT: I have reviewed all of the jury
9 instructions in *Apotex*, and I would also tell you that I'm
10 aware that the *Mylan* litigation was a bench trial and not a
11 jury trial. Jury trials are somewhat different from the
12 standpoint that the judge is charged with knowing the law in
13 a bench trial and sorting through the evidence. In a jury
14 trial, you all have to educate that jury as to the facts
15 that will then lead to the instructions of law from the
16 Court.

17 You all have a tremendous duty. It's not up to the
18 Court to straighten this all out for the jury. It's up to
19 you all. I'm not going to give any legal instructions upon
20 which you have not offered sufficient evidence to support
21 the jury instruction. So I've reviewed the *Apotex*
22 instructions, and they were very good.

23 MR. SOBOL: I won't make any further remarks, then.
24 I do think that Judge Goldberg navigated that quite well.
25 He did find that for the causation theory that was involved

1 in that case to allow in some later patent evidence, but
2 this Court has already read those decisions so I don't need
3 to tell you about it.

4 What I will say, this is my final remark with
5 respect to this motion, if I may, Your Honor, is this. This
6 Court and these lawyers, for both the plaintiffs and the
7 defendants, we all have legal education, we all have
8 experience in the law, we all have some background in patent
9 issues, and we can ourselves try to parse these issues apart
10 even in this antitrust case.

11 The plaintiffs' position is that given the fact
12 that this is something that happened two years after the
13 fact, and given the numerosity of the issues and how
14 different it is, it's completely well within your
15 discretion, under 403, and we would seek the Court to
16 exercise it, and we do not think it would be error in you
17 exercising your discretion under Rule 403 to say, you know
18 what, this is just too much to expect the jury to do. It
19 would be unduly prejudicial, far too confusing for the jury.
20 It would weigh your trial down because it is going to
21 require massive amounts of more testimony from witnesses,
22 documents, as you can see, because all of the things, the
23 differences I've indicated here obviously would have to be
24 paraded before the jury, and counsel fighting and struggling
25 to be able to have the jury in what I would suggest would be

1 a hopelessly confused mess of trying to figure out why we've
2 got literally a trial within a trial within a trial, because
3 we are supposed to be trying an antitrust case, and then we
4 will look a little bit at the merits of the Glenmark case,
5 in terms of looking at what the possibilities were of
6 Glenmark winning, but then we also, inside that second
7 trial, are now having a third trial, which is the trial of
8 the *Mylan* case, and we are not even trying the *Mylan* case.

9 Now we are putting the jury in a situation where
10 they are trying to compare two cases. I just think it is
11 too much, Your Honor. Thank you.

12 THE COURT: Thank you, Mr. Sobol.

13 Who is arguing for Merck?

14 MR. LIVERSIDGE: Your Honor, Sam Liversidge for the
15 Merck defendants.

16 THE COURT: You are arguing it, not Mr. Ismail?

17 MR. LIVERSIDGE: Correct, Your Honor. I have some
18 slides as well, if I can hand those up.

19 THE COURT: Certainly.

20 MR. LIVERSIDGE: Your Honor, good afternoon. Sam
21 Liversidge on behalf of the Merck defendants and arguing for
22 the defendants here today.

23 We appreciate the Court's time on this issue. This
24 is obviously an important issue for us. We appreciate the
25 opportunity to explain some of the background here and some

1 of the background around the evidence on the *Mylan* case.

2 I'd like to, if I could, just walk you through
3 quickly plaintiffs' basic claim on the inventorship issue in
4 the case because I think it helps the Court understand how
5 this evidence fits in.

6 If we can go to slide 3, I know you have already
7 seen this probably many times. This is the basic opinion
8 that Dr. Hrubiec is offering, which is that Merck was highly
9 likely to lose the case, and Glenmark was highly likely to
10 win. This is the foundational opinion for their case, and
11 this is used as a proxy for what Merck was thinking at the
12 time of the settlement. So they take an expert opinion
13 after the fact and use it as a proxy for what we would have
14 been thinking and expecting at the time of the settlement.

15 We go to slide 4, the entire basis for that opinion
16 is the inventorship claim, the improper inventorship
17 challenge, and they chose to make that the claim that forms
18 the basis of the 65 to 75 percent opinion that Dr. Hrubiec
19 is offering, of course, knowing that we went to trial on the
20 inventorship issue in the *Mylan* case.

21 And if I can go to slide 5, just so that the Court
22 understands because I'm not sure this has been briefed at
23 length, the inventorship claim in the Glenmark case was that
24 in the patent application, the original patent application,
25 Merck named five scientists as inventors. It named five.

1 And the claim was you failed to name a sixth inventor,
2 Dr. Afonso. That was the basic claim in the Glenmark case,
3 and that was the basic claim in the *Mylan* case; you should
4 have named Dr. Afonso.

5 THE COURT: That issue then predates the
6 settlement, so that would not be improper because that issue
7 then would predate the settlement; is that correct?

8 MR. LIVERSIDGE: That would predate the settlement.
9 All of the facts around these inventorship issues took place
10 in the 1990s, actually in the early '90s, so long before the
11 Glenmark case and the *Mylan* case.

12 THE COURT: But you can do a stipulation on
13 something like that. You don't need to present all this
14 evidence to the jury about inventorship patents. Just come
15 to an agreement and stipulate it to the jury. I mean, the
16 jury is just going to be confused by, you've got Stuart
17 Rosenblum, you've got Sundeep Dugar, you have got Duane A.
18 Burnett, you've got John W. Clader, you've got Brian A.
19 McKittrick, you've got Dr. Afonso, and just come to some
20 agreement over what the jury should know that was the issue
21 in the Glenmark case.

22 MR. LIVERSIDGE: Understood, Your Honor.

23 THE COURT: I'm not telling you you have to, but
24 I'm saying from my way of thinking that's the way you would
25 do something like that as opposed to spending your valuable

1 trial time and trying to educate a jury that probably you're
2 not going to have anybody on that jury that knows anything,
3 probably, I don't know. I don't know who the jury panel
4 even is, but I doubt you're going to have an antitrust
5 expert. If you do, you all will have stricken the person.
6 You're not going to have a patent expert on there or an
7 attorney. You will have that information, so the odds are
8 you're not going to have that kind of person on the jury.

9 I think all of this is just so much for a jury to
10 absorb, but go ahead.

11 MR. LIVERSIDGE: Thank you, Your Honor.

12 If we look at slide 6, speaking of the Glenmark
13 case, on slide 6 we see a description of what the
14 inventorship claim was in Glenmark, and this is
15 Dr. Hrubiec's testimony. The claim in Glenmark was that Dr.
16 Afonso should have been named an inventor on the '721 patent
17 because he possessed the operative method of making the
18 claimed compounds 4E and 4F. That was the inventorship
19 claim in Glenmark. He should have been named an inventor
20 because he came up with a way to make these compounds 4E and
21 4F.

22 If we go to slide 7, that is the issue that Judge
23 Linares decided in the *Mylan* case. Judge Linares determined
24 that Afonso did not contribute to the operative method of
25 making compounds 4E and 4F and that Afonso was not an

1 inventor of the compounds 4E and 4F.

2 Dr. Hrubiec's 65 to 75 percent opinion is premised
3 on the chances that Glenmark or Merck was going to win on
4 this issue.

5 THE COURT: But you didn't know at the time.

6 MR. LIVERSIDGE: We didn't know. But Judge
7 Linares' opinion is another opinion about how a reasonable
8 and competent patent lawyer would view these issues, and he
9 reached a very different conclusion than Dr. Hrubiec.

10 THE COURT: Why don't you just tell us? You've got
11 the reasonable and competent patent lawyers that were
12 involved in this. So why don't you just get up and tell
13 them? Why don't you just tell them to tell the story, if
14 the story is compelling? You've got those attorneys or
15 you've got those records, and you're claiming
16 attorney-client privilege. Mr. Hrubiec is an attorney,
17 isn't he, patent attorney?

18 MR. LIVERSIDGE: He is.

19 THE COURT: So what else are you going to do? In
20 other words, you've got the key to the evidence. You were
21 in the case. They had legal advice. They had your
22 attorneys, so you hold the key to it.

23 MR. LIVERSIDGE: Those attorneys are going to
24 testify, Your Honor, and they are going to testify to all of
25 the objective facts in the case that we believe show why we

1 would have won the Glenmark case.

2 THE COURT: The attorneys that were in the *Mylan*
3 case?

4 MR. LIVERSIDGE: The attorneys from Merck that were
5 involved in *Mylan* and in Glenmark, they are going to
6 testify.

7 THE COURT: Who are they?

8 MR. LIVERSIDGE: Paul Matukaitis is one.

9 THE COURT: Can you spell the last name?

10 MR. LIVERSIDGE: I think so. M-a-t-u-k-a-i-t-i-s.

11 THE COURT: All right.

12 MR. LIVERSIDGE: I think I got that right. And
13 then Lisa Jakob is the other one, J-a-k-o-b. Those two
14 attorneys are going to testify.

15 THE COURT: What cases were they involved in?

16 MR. LIVERSIDGE: They were both involved in the
17 Glenmark case and the *Mylan* case.

18 THE COURT: They represented Merck?

19 MR. LIVERSIDGE: Correct.

20 THE COURT: I've seen Ms. Jakob's name, but has the
21 other name been in anything? Maybe he just hasn't been in
22 something that I read.

23 MR. LIVERSIDGE: The other name was in the briefing
24 on summary judgment because he was involved in negotiating
25 the settlement, Mr. Matukaitis. Ms. Jakob was the lead

1 attorney overseeing the day-to-day litigations, and she is
2 scheduled to testify the first week of trial, perhaps it's
3 the beginning of the second week. The plaintiffs told us
4 they intended to call her on Thursday.

5 THE COURT: You are talking about the plaintiffs
6 presenting this person?

7 MR. LIVERSIDGE: They are calling our witness in
8 their case. They are calling Ms. Jakob in their case.

9 THE COURT: We will see if they open the door. Go
10 ahead.

11 MR. LIVERSIDGE: Your Honor, I'm giving you this
12 background on the claim, and I guess let me just skip ahead
13 on the slides. I've got a number to cover.

14 If we go to slide 11, it's not just that we believe
15 Judge Linares resolved the inventorship, the underlying
16 inventorship that was also in play in the Glenmark case,
17 it's that Dr. Hrubiec intends to make findings based on the
18 evidence and tell the jury that it is his opinion that a
19 reasonable and competent lawyer would have reached the
20 following conclusions about the evidence when a lot of the
21 things he's saying, a lot of the opinions he has are
22 directly contrary to the opinions of Judge Linares. They
23 are more specific findings than just the patent was upheld
24 as valid and enforceable.

25 THE COURT: I'm not going to let you put in a

1 judge's, that's highly prejudicial to tell a jury that a
2 federal judge found this in another case, and they haven't
3 heard that case. I haven't heard that case. I certainly
4 haven't read all of the transcripts for it. So that would
5 be so prejudicial as to tell a jury, by the way, that's like
6 saying this is the law of this case. The judge determines
7 the law of this case.

8 MR. LIVERSIDGE: We certainly are not proposing to
9 have it presented as the law of the case, Your Honor. But
10 Dr. Hrubiec intends to say things like, reaching the
11 conclusion that Dr. Afonso was the first scientist who had
12 an operative method of making compounds 4E and 4F, when
13 Judge Linares determined that Dr. Afonso did not first
14 conceive of the operative method of making these compounds.

15 THE COURT: I'm not going to be bound by Judge
16 Linares. He is a fine judge, but one Court is not going to
17 be bound by the findings of a judge on something like that
18 that involved all of these different facts and a change in
19 the patent, a re-issue of the patent. You've got a re-issue
20 of the patent, and that is something that you cannot get
21 around.

22 MR. LIVERSIDGE: Okay. Well, Your Honor, we are
23 not talking about being bound as much as it is an opinion of
24 another reasonable and competent lawyer.

25 THE COURT: He is not a lawyer. Judge Linares is

1 no longer a lawyer. Judges can't practice law. They are no
2 longer lawyers. I have no idea what his background was in
3 the practice of law. Just simply not going to allow it.
4 You can count on that right now, that I'm not going to let
5 that come in, and I would call down the attorney, strike the
6 evidence, and instruct the jury that it was improper
7 evidence, contrary to the Court's rulings, and they are not
8 to be bound by it, they are to totally ignore that evidence
9 in deciding the issues proposed in the case. You're not
10 going to issue another judge's opinion in this case.

11 MR. LIVERSIDGE: Understood.

12 THE COURT: A finding like that. You are just not
13 going to do that. I hope you weren't planning it.

14 MR. LIVERSIDGE: Understood, Your Honor.

15 Let me skip to the re-issue since we spent time on
16 that. If we go to slide 16, and Mr. Noona mentioned this
17 point. One of the reasons why we don't think the re-issue
18 changed the inventorship challenge here is because you can't
19 undo a claim for inequitable conduct by re-issuing the
20 patent, and that's why it was necessary for Judge Linares to
21 rule on the claim that Dr. Afonso contributed to the methods
22 of making 4E and 4F, even though the plaintiffs say those
23 compounds were dropped. And that's why it was necessary for
24 him to determine whether Dr. Afonso was an inventor on the
25 patents that were at issue in Glenmark even though the

1 patent had been re-issued and changed.

2 So if I skip to my next slide, the very basic
3 slide, slide 17, these are the Zetia patents. The Court has
4 probably seen this, but the original patent was the '115
5 patent issued back in 1998. That patent then got re-issued,
6 and in 2002 it became the '721. And the '115 and the '721
7 patents were the patents that were at issue in the Glenmark
8 case. Those were the patents at issue in that case.

9 Then before the *Mylan* trial, the patent got
10 re-issued and became the '461. But the claim about
11 inventorship is that Dr. Afonso should have been named an
12 inventor on the original patent, the '115. Dr. Afonso was
13 gone from the company for almost a decade before the
14 re-issue patent became the '461.

15 The question was should he have been named an
16 inventor on that original patent, the '115? And that's why
17 when you go to slide 18, you see that this is the testimony
18 of Dr. Hrubiec. You understand that Judge Linares made a
19 finding that Dr. Afonso was not a co-inventor of the '115
20 and its subsequent '721 patents.

21 Those are the same patents that were at issue in
22 the Glenmark case because he had to make that determination
23 to resolve the inventorship challenge. The patent did
24 change in the re-issue. We are not contesting that. We
25 acknowledge that there were some changes in the patent.

1 THE COURT: Well, enter into a stipulation, then.

2 MR. LIVERSIDGE: Understood, Your Honor.

3 THE COURT: That's the way I would see resolving
4 this, is that there was a court finding that he was not a
5 co-inventor, and something like that, whatever you all can
6 agree. I'd have to look at it, but enter into a
7 stipulation. There are certain things that are facts here,
8 and you can enter into a stipulation.

9 MR. LIVERSIDGE: We can propose a stipulation that
10 has the findings like you see here on slide 18. He made a
11 finding that Dr. Afonso was not a co-inventor of the '115
12 and '721 patents, and Dr. Hrubiec agrees with that.

13 THE COURT: You don't have to say Judge Linares.
14 You can say a finding was made in such litigation. You
15 don't have to refer to the judge. A finding was made in the
16 Mylan litigation and when it was made. As a result of that
17 finding, you all would have to write the stipulation, but
18 you can say a finding was made in a case without saying a
19 judge. It's one thing to argue that to a judge. In other
20 words, a lot of times somebody will come into your court and
21 say, Judge Davis did so and so, or the Fourth Circuit with
22 Chief Judge Gregory writing the opinion did. That's
23 permissible before a Court. But the prejudicial value of
24 that, when a judge is sitting in a federal courtroom with a
25 federal jury, it gives it some inherent status that it

1 shouldn't have in another case.

2 Anyway, there are ways to get around it. You can
3 say "in that case," and I would certainly consider that as a
4 stipulation from the parties without saying Judge Linares.

5 MR. LIVERSIDGE: Certainly. We will undertake the
6 initiative to prepare a proposed stipulation on those facts
7 and those rulings in *Mylan*.

8 THE COURT: I think that was one of the words of
9 advice I was going to give to both parties at the end of
10 this, that maybe a little bit of time you all have left
11 might be well spent trying to reach some resolution on this
12 stipulation that would resolve, if not all of it, at least
13 part of it. Go ahead.

14 MR. LIVERSIDGE: Thank you. Your Honor, if I
15 could, I spent a little bit of time talking about the
16 likelihood of success opinion and why we think this evidence
17 is relevant. I just want to mention a couple of other areas
18 where we think this evidence comes into play in an important
19 way in the case.

20 THE COURT: All right.

21 MR. LIVERSIDGE: If I can move to slide 32. I have
22 a lot of slides. It's not just Dr. Hrubiec that we need to
23 cross-examine with this evidence. We are dealing with
24 economist models that they are presenting in the case that
25 drive the alternative entry dates and the damages in the

1 case, and they make a number of fundamental assumptions in
2 those models that drive damages and that drive the
3 alternative entry dates, and some of them bring into play in
4 a significant way the *Mylan* evidence and the *Mylan* case.

5 For example, this is Dr. McGuire, the chief
6 economist that the direct purchasers are going to bring, and
7 he has an economic model that he is going to present, and he
8 assumes in that model that when Merck settled the case with
9 Glenmark, when it settled the case, that it expected that it
10 was going to maintain exclusivity all the way to December of
11 2016. That's a fundamental assumption in his model, and you
12 can see his deposition testimony here.

13 In other words, Merck thought it was buying itself
14 exclusivity all the way to December of 2016, and they valued
15 the settlement to Merck based on that assumption. They say
16 that the settlement was worth \$2.8 billion to Merck because
17 Merck thought, when it settled with Glenmark, it was going
18 to have exclusivity without any generic competition all the
19 way to December of 2016.

20 But, of course, Merck had to win the *Mylan* case in
21 order for that to be true. If Merck lost the *Mylan* case,
22 not only was *Mylan* going to be able to enter the market but
23 Glenmark was going to be able to enter as well, and so this
24 is not a correct assumption. You cannot assume, based on
25 the settlement, that Merck was going to maintain

1 exclusivity. That only happens if Merck wins the *Mylan*
2 case, because this was the Ezetimibe patent that was at
3 issue in *Mylan*, and it's undisputed that if Merck lost that
4 case, Glenmark was going to come in.

5 We can see the testimony on slide 34 from
6 Dr. McGuire. "Do you understand that Glenmark would have
7 been entitled to enter the market with its generic version
8 of Zetia if *Mylan* had prevailed in its litigation against
9 Merck and invalidated Merck's patent covering Zetia?"

10 "That's my understanding."

11 So they are going to go in front of the jury and
12 assume we had zero risk of having generic competition
13 between the time of the settlement and December of 2016. We
14 have to be able to counter that by pointing out that we
15 actually went to trial in the *Mylan* case on the Ezetimibe
16 patent. Whatever you want to say about the differences in
17 the patent, it was the patent covering Ezetimibe, it would
18 have allowed Glenmark to enter the market.

19 How does Dr. McGuire deal with this issue of the
20 *Mylan* litigation? On slide 33, we can see. "How did they
21 know there was not going to be any generic entry after the
22 settlement with Glenmark?"

23 "Answer: Because they had an entry date of
24 December 12, 2016."

25 "And they had ongoing litigation with other

1 generics, including *Mylan*, on the same patent, right?"

2 "That's true. They must have thought they had a
3 very high chance of success."

4 "Okay.

5 "In the *Mylan* litigation."

6 THE COURT: But isn't that what settlement is all
7 about? You roll the dice? In other words, settlement,
8 whenever parties settle, there is not certainty. You settle
9 based upon your assessment, whether you're in an antitrust
10 case, a patent case, a slip and fall case. You settle a
11 case, you settle it based upon your assessment of the
12 strength of your case and the weaknesses of your case at the
13 time. You can't control what happens after the settlement.

14 Yes, a post-settlement might then, in hindsight, it
15 is like looking back at something you've done. You
16 certainly wish you could change it, but you can't. You
17 don't get do-overs. So the problem here is that you settle
18 it, and that something that happens in the future occurs,
19 you don't know that at the time you're settling it. That is
20 what settlement is all about, and I guess you call it
21 hornbook law in law school where you can't talk about
22 certain issues of settlement in cases.

23 You can look at the reverse. You can't talk about
24 certain issues after a case had settled. But, in any event,
25 that's what settlement is. All of us as lawyers knew it,

1 you as lawyers know it, and that's why you settle. Things
2 may not go in your favor.

3 MR. LIVERSIDGE: Understood, Your Honor.

4 This is more a point about countering the
5 fundamental assumptions that their experts are making in
6 order to value the settlement. If we look at slide 35, we
7 see that as of the time of the settlement, they are saying,
8 when you settled with Glenmark, you had no threat of
9 exclusivity, zero risk to you until December of 2016, and
10 that's how they valued the settlement. And we want to be
11 able to point out to this expert, the only reason that's
12 true is because we actually went to trial against *Mylan* and
13 won it. If we'd lost, there would have been generic
14 competition years earlier. It is after the settlement
15 evidence, but it is fundamental to countering an assumption
16 that they are using to come up with their damage estimates.

17 It's also the case that they have these
18 contradictory assumptions that do not hold together. If we
19 look at slide 36, they're basically saying that we thought
20 we had a hundred percent chance of winning *Mylan* but only 25
21 to 35 percent chance of winning Glenmark.

22 THE COURT: They are going to say that because you
23 got your patent changed or you got it re-issued. That would
24 be my immediate reaction without having heard the testimony.

25 MR. LIVERSIDGE: I think you are correct. I think

1 they are going to say that. But it's also the case that if
2 we had lost that case, that there would have been generic
3 competition, including from Glenmark. We think it's
4 important for us to be able to raise that issue to counter
5 these assumptions.

6 I would point out on the same subject, if we go to
7 slide 41.

8 THE COURT: I think that's motion *in limine* number
9 15 that Judge Miller just ruled on. I don't think that this
10 hearing was scheduled for that, and, in fact, if I were you,
11 and I was looking at my time, I might not spend a lot of
12 time between now and the trial on that. I thought, to both
13 sides, I thought it was a very good opinion. I wouldn't
14 spend a lot of time on it between now and trial. But if you
15 want to use your time today talking about it, you can.

16 MR. LIVERSIDGE: I'll just make one final point on
17 this, Your Honor. If we look at slide 41, it is the case
18 that this settlement agreement had an acceleration clause,
19 which we believe is one of the procompetitive aspects of the
20 settlement. It gave an entry date of December 12th, 2016,
21 or an earlier date if Merck's patent is invalidated.

22 So if *Mylan* had won that litigation against Merck
23 under the terms of the settlement between Merck and
24 Glenmark, Glenmark would have been able to enter the market
25 pursuant to the terms of the agreement. And so you cannot

1 arrive at the entry date under the terms of the settlement
2 agreement at issue without understanding whether Merck won
3 the *Mylan* litigation or not.

4 So we think it's going to be important to explain
5 at some level to the jury that we did have another
6 litigation. If we'd lost that litigation, Glenmark would
7 have been able to enter even earlier than they did, and the
8 only reason they didn't is because we went to trial and won
9 against them. So we think this is another area where it's
10 important that we be able to tell the jury something about
11 *Mylan*, what happened in that case and the result, because
12 it's fundamental to understanding what the entry date was
13 under the settlement.

14 Your Honor, thank you very much for the time.

15 THE COURT: Let me look at my notes and see if I
16 have anything else I want to ask you before we start into
17 any evidence. That's all.

18 MR. LIVERSIDGE: Thank you, Your Honor.

19 THE COURT: Then, Mr. Sobol, you're going to call
20 Dr. Hrubiec?

21 MS. KRISTEN JOHNSON: I am, Your Honor.
22 Dr. Hrubiec can take the stand, with your permission.

23 THE COURT: Can you come up and identify yourself,
24 please.

25 I'm talking about the attorney.

1 MS. KRISTEN JOHNSON: Apologies, Your Honor,
2 Kristen Johnson for the plaintiffs.

3 THE COURT: All right.

4 (Witness was sworn.)

5 MS. KRISTEN JOHNSON: If I may, Your Honor, I have
6 copies for the Court and for the witness as well.

7 THE COURT: I think I had instructed four copies.

8 MS. KRISTEN JOHNSON: Yes, Your Honor.

9 I apologize. We apparently passed up the wrong
10 binders, Your Honor. I apologize.

11 THE COURT: Give these back.

12 MS. KRISTEN JOHNSON: Thank you, Your Honor, and I
13 believe the witness' has been corrected.

14 ROBERT HRUBIEC, called by the Plaintiff, having
15 been first duly sworn, was examined and testified as
16 follows:

17 DIRECT EXAMINATION

18 BY MS. KRISTEN JOHNSON:

19 Q. Good afternoon, Dr. Hrubiec.

20 A. Good afternoon.

21 Q. Please state your name.

22 A. My name is Robert Hrubiec.

23 Q. Can you spell that.

24 A. H-r-u-b-i-e-c.

25 Q. Please briefly describe your professional background as

1 it relates to the opinions you're offering in this case.

2 A. I have a Ph.D. in synthetic organic chemistry. I did
3 post-doctoral work in synthesizing organic compounds for use
4 as pharmaceuticals. I then moved on to industry, worked for
5 a biotech company, again, synthesizing more compounds for --
6 to be used as pharmaceuticals. Did that for about five or
7 seven years.

8 After that I moved on to a large pharmaceutical
9 company in North Carolina, which is now GSK, and started my
10 patent career there, first as a patent agent, and then I went
11 to law school at night, and once I received my JD, I became a
12 patent lawyer.

13 I worked for the company initially drafting and
14 prosecuting patent applications in front of the patent
15 office. I also did a lot of work evaluating third-party
16 patents for -- to determine their strengths and weaknesses.
17 And after that I moved on. I did that for about ten years
18 and then moved on to a company in Pennsylvania, Cephalon, and
19 headed up their patent department there, where besides being
20 responsible for the company's patent portfolio
21 prosecution-wise, I continued to advise the company on the
22 strengths and weaknesses of third-party patents as well as
23 advising upper management of that company as to the
24 likelihood of success in their patent litigation cases.

25 After that I left Cephalon and started my consulting

1 business about ten years ago or so, consulting with clients
2 on various patent matters.

3 Q. Who hired you in this litigation?

4 A. I was hired by, I believe it was your firm.

5 Q. On behalf of which parties?

6 A. On behalf of the plaintiffs.

7 Q. What were you asked to do with respect to the outcome of
8 the Glenmark litigation?

9 A. I was asked to review the Glenmark record from both
10 parties, including expert testimony, depositions, expert
11 reports, transcripts, court orders, and other materials, as
12 well as reviewing the '721 patent, the specification, the
13 claims of the '721 patent, as well as its progeny, starting
14 from the -- what was called the '440 patent application,
15 including the '115 patent and the '721 patent, re-issue
16 patent.

17 Q. Having reviewed those materials, were you asked to do
18 anything else?

19 A. Having reviewed those materials, I was asked to provide
20 my opinions.

21 Q. If you turn to Paragraph 23 in your report, it should be
22 the first tab in the binder provided.

23 A. 23?

24 Q. Yes, sir.

25 A. I'm there.

Hrubiec, R. - Direct

60

1 THE COURT: Just a minute. You said tab 23?

2 MS. KRISTEN JOHNSON: Paragraph 23 in Dr. Hrubiec's
3 report. It should be the first tab, Your Honor.

4 THE COURT: Yes.

5 BY MS. KRISTEN JOHNSON:

6 Q. What were you asked to do with respect to advising a
7 client?

8 A. I was asked to provide an opinion from the perspective of
9 reasonable and competent patent counsel as to how I would
10 have advised the client at the time in May of 2010 as to the
11 likelihood of Schering prevailing -- prevailing in a lawsuit
12 and showing that their '721 patent -- I'm sorry -- showing
13 that Glenmark infringed one or more claims of a Schering
14 valid and enforceable patent.

15 Q. When you say a lawsuit, do you understand that to be the
16 Glenmark litigation?

17 A. Yes, that was in the Glenmark litigation.

18 Q. And when you say Schering, who's Schering?

19 THE COURT: I know. Before the jury, you would
20 have to present that Schering is now part of Merck.

21 MS. KRISTEN JOHNSON: Thank you, Your Honor. I
22 will move it along.

23 THE COURT: You can skip that.

24 BY MS. KRISTEN JOHNSON:

25 Q. Do Paragraph 23 and Paragraph 23.1 accurately describe

1 your assignment with respect to the outcome of the Glenmark
2 litigation?

3 A. Yes, they do.

4 Q. Were the views of Merck's counsel, as of May 2010,
5 available to you in doing your work?

6 A. I'm sorry. Can you repeat that?

7 Q. Sure. In doing your work in this case, did you have
8 available to you what Merck's lawyers thought about the
9 merits of the Glenmark litigation as of May of 2010?

10 A. No, I didn't.

11 Q. Did you have available to you the views of Glenmark's
12 lawyers, as to what they thought about the likelihood of
13 succeeding in the Glenmark litigation as of May of 2010?

14 A. No, I did not have those either.

15 Q. Were you able to form opinions about how reasonable and
16 competent patent counsel would have advised a client about
17 the likelihood of Schering succeeding as of May of 2010?

18 A. Yes.

19 Q. What was your opinion?

20 A. My opinion was that reasonable and competent patent
21 counsel advising Schering and Glenmark as of May 2010 would
22 have advised the party that Glenmark had a 65 to 75 percent
23 likelihood of prevailing against -- I'm sorry, 65 to 75
24 percent likelihood of prevailing in that case.

25 Q. In forming those opinions, that opinion, did you rely on

1 any post-May 2010 facts about the *Mylan* litigation?

2 A. No, I did not rely on any post-May 2010 facts or
3 information.

4 Q. How are post-May 2010 facts about the *Mylan* litigation
5 relevant to your opinion about how reasonable and competent
6 patent counsel would have advised the client about the
7 likelihood of Schering succeeding in May of 2010?

8 A. They're not relevant at all.

9 Q. Why not?

10 A. First, they didn't exist as of May 2010. Second, and
11 perhaps even more importantly, there were several important
12 and significant differences between the Glenmark case and the
13 *Mylan* case.

14 Q. Like what?

15 A. First, it was a different patent, as we've heard. The
16 inventors were different in the two cases. The experts were
17 different in the two cases. The testimony that the experts
18 provided was different. The lawyers were different in the
19 two cases. The law was different in the two cases. The
20 defense was different in the two cases.

21 Q. So I want to break --

22 A. Go ahead.

23 Q. Had you finished your answer, sir? I apologize.

24 A. Yes, I did.

25 Q. I want to break that down a little. How is the patent

1 different, from your perspective?

2 A. Well, the re-issue patent in *Mylan* no longer contained
3 claims covering the compounds 4E and 4F.

4 Q. Why does that matter?

5 A. Well, that matters because now they had to prove, for
6 inventorship purposes, that Dr. Afonso was an inventor of
7 Ezetimibe.

8 Q. Was that an argument that Glenmark had made, that
9 Dr. Afonso was an inventor of Ezetimibe?

10 A. In the Glenmark case? No, not at all. They were arguing
11 that he was an inventor of the compounds 4E and 4F only.

12 Q. What did Merck cite as the reason that it sought
13 re-issue?

14 A. They cited an issue that was presented in the
15 underlying -- in the earlier Glenmark case.

16 Q. You said that the inventors were different as between
17 Glenmark and *Mylan* cases?

18 A. Totally.

19 Q. What did you mean?

20 A. Well, in Glenmark, Merck was putting forth Dr. Rosenblum
21 as the inventor of the compounds 4E and 4F; whereas,
22 subsequently in *Mylan*, Merck was now putting on Drs. Clader
23 and Burnett as the ones who invented 4E and 4F.

24 Q. You said the experts in *Mylan* were different than the
25 experts in Glenmark. What did you mean?

1 A. I did, yes. Well, I meant in Glenmark, the experts, the
2 expert on inventorship, on the inventorship issue, was a
3 Dr. Brisbois. In the subsequent *Mylan* case, Merck had
4 switched and changed and now were providing a Dr. Myers,
5 Dr. Rosenblum, and Dr. Roush as experts and, in fact,
6 witnesses for the inventorship issue. So they went from one
7 expert in Glenmark to three in *Mylan*.

8 Q. And I think you may have misspoken, so let me clarify.
9 So who were the three experts in *Mylan*? If I've got it
10 right, it's Dr. Brisbois, Dr. Roush, and Dr. Myers?

11 A. Correct.

12 Q. Okay. Why would it matter if they changed the experts in
13 *Mylan*?

14 A. It matters because those experts would be providing
15 different testimony in different fashions in *Mylan* than they
16 would in Glenmark.

17 Q. And, in fact, did Dr. Roush in *Mylan* provide different
18 additional testimony to what Dr. Brisbois had provided in
19 Glenmark?

20 A. Yes, he did. Do you want me to continue?

21 Q. Please. Thank you.

22 A. Dr. -- I've got to keep all the players and the parties
23 straight. Dr. Roush in Glenmark, he provided expert
24 testimony as to Dr. Burnett being able to make another
25 compound, 8F, and if Dr. Burnett was able to make that

1 compound, then Dr. Burnett would be able to make the
2 compounds 4E and 4F. That was the basis of Dr. Roush's
3 testimony, which Judge Linares and the Court in *Mylan* heavily
4 relied on and actually specifically referenced their
5 testimony.

6 Q. So if I've got it right, then, in the *Mylan* case,
7 Dr. Roush offered an opinion that if one could make compound
8 8F, as Dr. Burnett had done, one could make compounds 4E and
9 4F that was in *Mylan*, correct?

10 A. That was Dr. Roush's testimony -- testimony in *Mylan*,
11 correct.

12 Q. In the Glenmark case, Dr. Roush also put in an expert
13 opinion?

14 A. Yes, he did.

15 Q. Did it address inventorship?

16 A. No, it did not. Dr. Roush was providing expert testimony
17 in Glenmark to a different issue.

18 Q. I take it, then, that Dr. Roush's Glenmark reports did
19 not offer the argument that if one could make compound 8F,
20 one could make compounds 4E and 4F?

21 A. He did not provide that testimony.

22 Q. You said that there were different lawyers in *Mylan* than
23 in Glenmark?

24 A. Correct.

25 Q. How did the lawyers differ?

1 A. Well, certainly my understanding was that the Merck
2 lawyers were the same. However, in Glenmark, Glenmark had
3 their lawyers, and in *Mylan*, *Mylan* had their own different
4 lawyers.

5 Q. Did *Mylan* lawyers offer any different theories about the
6 case --

7 A. Yes.

8 Q. -- as Glenmark's lawyers?

9 A. They did, yes.

10 Q. How so?

11 A. In *Mylan*, because of the change in the patent, *Mylan* had
12 to argue that Dr. Afonso was not only an inventor on the 4E
13 and 4F compounds, as they did in Glenmark, they had to also
14 argue that Dr. Afonso was also an inventor of the other
15 compound Ezetimibe in that *Mylan* patent.

16 Q. And Ezetimibe is the generic name for the active
17 ingredient in the drug Zetia, right?

18 A. That's correct.

19 Q. How did the defenses differ, if at all, as between
20 Glenmark and *Mylan*?

21 A. The defenses in *Mylan* -- I'm sorry, the defenses in
22 Glenmark -- Glenmark is on my left, *Mylan* is on my right.
23 The defenses in Glenmark were threefold: Glenmark was
24 defending on patent term extension, obviousness-type double
25 patenting, and also inventorship; whereas, in *Mylan*, *Mylan's*

1 defenses were only inventorship.

2 Q. Am I understanding, then, that in Glenmark, the generic
3 had three paths to victory, potential paths to victory?

4 A. Sure, yes. They had three defenses, so they had three
5 shots on goal, if you will.

6 Q. And in *Mylan*, there were how many shots on goal
7 available?

8 A. They had one defense and one shot.

9 Q. Now, by the way, how do you know what Glenmark's defenses
10 were in the Glenmark litigation?

11 A. Because I reviewed the pretrial briefs of both Glenmark
12 and Merck in the Glenmark case.

13 Q. Did you review similar briefing from the *Mylan* case?

14 A. Yes, I reviewed those pretrial briefs as well.

15 Q. In your report, you analyzed each of Glenmark's defenses
16 and assigned each a probability of success?

17 A. I did, correct.

18 Q. Which of the defenses did you ascribe your overall
19 opinion of success -- terrible question. I can do better.

20 Which of those defenses did your overall opinion
21 about the chance of success as to how reasonable and
22 competent patent counsel would have advised a client in May
23 of 2010 as to Merck's chance of succeeding and proving its
24 case in Glenmark?

25 A. I based my opinion on the overall chance of success based

1 on the opinion regarding inventorship.

2 Q. Dr. Hrubiec, if facts about what happened in the *Mylan*
3 litigation are not relevant to your opinion about what
4 reasonable and competent patent counsel would have advised in
5 May of 2010, why do you sometimes refer to such facts in your
6 opening report?

7 A. Well, I wanted to be complete. My marching instructions
8 were to provide an opinion based on the record as it existed
9 in 2010, but I was made aware of the later-occurring *Mylan*
10 case and Judge Linares' decision in that case and opinion.

11 So I just felt compelled to make -- to look at that
12 case and to make sure that there was nothing in that case
13 that would cause me to change my opinions with regard to the
14 Glenmark defenses. I wanted to make sure no stone was
15 unturned so I could feel confident that my opinions and my
16 conclusions were rock solid.

17 Q. What was it that you expected to find in the *Mylan* case
18 that could have changed your opinions?

19 A. I didn't expect to find anything when I started. I just
20 went in with an open mind and read all the relevant documents
21 and concluded that the *Mylan* case was -- there were so many
22 differences, and so many significant differences that it
23 wouldn't apply to what was happening in Glenmark.

24 Q. If I could direct you to Paragraph 26 of your report,
25 Doctor.

1 A. Okay.

2 Q. You state in Paragraph 26, in part, "I sometimes address
3 subsequent events and precedent (including, but not limited
4 to, developments in the caselaw and the *Schering/Mylan*
5 litigation) but do not consider them when opining on the
6 advice reasonable and competent patent counsel would have
7 offered prior to the settlement in May 2010 because such
8 developments would not have been reasonably foreseeable by
9 the parties or their counsel in May 2010."

10 Is that an accurate statement, sir?

11 A. Yes, it is.

12 Q. If I can direct you to Paragraph 202 -- I'm sorry, 244.
13 Well, it's a little tricky. I apologize. Let's do 202, and
14 it's footnote 156 that should be on that page.

15 THE COURT: Page 202, Paragraph 202?

16 MS. KRISTEN JOHNSON: Paragraph 202, Your Honor.

17 THE WITNESS: Page 202?

18 BY MS. KRISTEN JOHNSON:

19 Q. Paragraph 202, footnote 156.

20 A. Paragraph 202, footnote 156. My footnote 156 is on Page
21 103.

22 Q. Let's try Paragraph 244.

23 THE COURT: First of all, what footnote are we
24 looking at? Let's start it that way.

25 MS. KRISTEN JOHNSON: 156, Your Honor.

1 THE WITNESS: Bottom of Page 103.

2 THE COURT: All right. Go ahead.

3 BY MS. KRISTEN JOHNSON:

4 Q. Would you read Paragraph 244 for me, sir.

5 A. Certainly. "As such, in my opinion, around the time of
6 settlement a reasonable patent counsel would find there was a
7 high likelihood that: One, inventorship would not be
8 corrected -- could not be corrected because Afonso
9 intentionally deceived the PTO, and, therefore, RE '721
10 patent was invalid; and, two, Rosenblum's breach of his duty
11 of good faith and candor constituted inequitable conduct and
12 rendered the entire patent unenforceable."

13 Q. In that paragraph, sir, are you making a finding as to
14 whether Dr. Afonso is, in fact, an inventor or not?

15 A. No, I'm not.

16 Q. What are you doing?

17 A. I am simply saying that a factfinder -- this is what a
18 factfinder could find, could determine. It wasn't my job to
19 make that determination.

20 Q. If the analysis that you took in forming that opinion --
21 I'm sorry, strike the question. I forgot why we were here
22 for a minute. I apologize.

23 Footnote 156, do you have that?

24 A. Yes.

25 Q. What does it state?

1 A. Do you want me to read it?

2 Q. Yes, please.

3 A. "The subsequent *Mylan* opinion and the upheld decision on
4 appeal do not change my analysis because the later findings
5 of a court on the same or similar issues would not have
6 impacted what the parties knew and considered at time of
7 settlement."

8 THE COURT: Let me just interject something here
9 that causes some confusion to the Court. First of all, an
10 expert's opinion doesn't go before the jury, only the
11 expert's testimony. There has been all of this drama
12 created over the statements in the report, and there is
13 nothing to indicate that they would be part of the
14 testimony.

15 So until they're part of the testimony, Merck and
16 the defendants are claiming, oh, we can't defend. I don't
17 understand that because there is nothing here that indicates
18 he would say this on the stand. Until he says this -- and
19 this was part of their case -- why would the *Mylan*
20 litigation come in after the fact? Because you are putting
21 the position that they are going to get on the stand first
22 and try to make distinctions between the Glenmark litigation
23 and the *Mylan* litigation.

24 There is nothing here that I've heard so far that
25 would indicate that that's the case. I've repeatedly said

1 if the door is opened, then that's a different story. But
2 you defend upon the case presented by the plaintiffs. The
3 plaintiffs rebut upon the defense presented by the
4 defendants. There is nothing here that would tell me that
5 he's going to get on the stand, and, in the case in chief,
6 talk about all of this with the *Mylan* litigation that
7 happened after the settlement when he's repeatedly saying
8 here, it doesn't affect my opinion. That's point one.

9 Point two is that you're basing a lot of this on
10 his percentages of success at the time of the settlement and
11 what a reasonable patent attorney would say. Then you're
12 going to, I imagine, cross him pretty strenuously on, how do
13 you know what a reasonable patent attorney would say, and
14 you know because you have that evidence.

15 I don't know, but I may be inclined to instruct the
16 jury that Merck is the same party ultimately in both cases
17 and that they have the records for what was being advised,
18 that there is better evidence to rebut this. Because you
19 are going to attack him on percentages that he's had to make
20 because you refuse to produce the evidence.

21 I'm just saying that as an observation. I'm not
22 saying I'll give that instruction. But certainly a jury
23 would be scratching their head and saying, well, he's making
24 a prediction this was going on, and what were the attorneys
25 doing? That would be the natural commonsense reaction of a

1 jury, and a jury is instructed that they can use their
2 common sense in judging any evidence.

3 It's 3:00. We have been in here over two hours.
4 We are going to take a 15-minute recess, and we will resume
5 with Dr. Hrubiec's testimony.

6 (Recess from 3:03 p.m. to 3:21 p.m.)

7 THE COURT: You may resume your examination.

8 MS. KRISTEN JOHNSON: Thank you, Your Honor.

9 BY MS. KRISTEN JOHNSON:

10 Q. Dr. Hrubiec, does any part of the opinion that you intend
11 to present to the jury about how a reasonable and patent
12 counsel -- let me correct my question.

13 Is there any part of the opinion that you intend to
14 give to the jury about how reasonable and competent patent
15 counsel would have advised the client about Glenmark that
16 requires you to rely on or discuss anything post-May 2010
17 about the *Mylan* litigation?

18 A. Nothing whatsoever.

19 Q. So I take it, then, that in offering an opinion about how
20 reasonable and patent counsel would have advised about
21 Glenmark, in your view, you don't need to talk about what
22 happened in the *Mylan* litigation?

23 A. Not at all.

24 Q. And so if you're not asked anything about the *Mylan*
25 litigation, including post-2010 facts about the *Mylan*

1 litigation, you're not going to testify about the *Mylan*
2 litigation?

3 A. No, I won't.

4 MS. KRISTEN JOHNSON: Thank you.

5 THE COURT: Mr. Liversidge.

6 MR. LIVERSIDGE: Thank you, Your Honor. We have
7 some of our own binders, I hate to say.

8 THE COURT: That's okay. There are two separate
9 binders, and the witness should have two, the courtroom
10 deputy, the law clerk, and the Court.

11 MR. LIVERSIDGE: Hopefully, everybody has it. It's
12 a report and deposition and then a separate binder with some
13 documents. It's a lot of documents for not a lot of
14 questions, so, hopefully, I can move pretty quickly.

15 May I proceed, Your Honor?

16 THE COURT: Certainly.

17 CROSS-EXAMINATION

18 BY MR. LIVERSIDGE:

19 Q. Good afternoon, Dr. Hrubiec.

20 A. Good afternoon.

21 Q. The patent at issue in the Glenmark case was the '721
22 patent, correct?

23 A. That's correct.

24 Q. And the '721 was a re-issue of the '115 patent, correct?

25 A. That's correct, it was a re-issue.

1 THE COURT: Excuse me for a minute. There are
2 actually three. You've done a binder, and then I don't know
3 what you call these with it.

4 MR. LIVERSIDGE: Spiral-bound, correct. There are
5 three separate.

6 THE COURT: I just want to be sure everybody is on
7 the same page and has them.

8 All right. That's fine.

9 BY MR. LIVERSIDGE:

10 Q. Just to re-set, Dr. Hrubiec, the patent at issue in the
11 Glenmark case was the '721 patent, correct?

12 A. That's correct.

13 Q. And that patent was a re-issue of the '115 patent,
14 correct?

15 A. Yes.

16 Q. And you understand that the Court in the *Mylan* case found
17 that Dr. Afonso was not a co-inventor of those '115 and '721
18 patents, correct?

19 A. While the Court did make that conclusion, it was based on
20 a very different record and facts.

21 Q. Well, I understand that you think it was different, but
22 the finding was that Dr. Afonso was not an inventor of the
23 patents that were at issue in the Glenmark case, right?

24 A. Again, based on a different set of facts, yes.

25 Q. And you don't actually know if the factual record

1 relating to whether Dr. Afonso should have been named an
2 inventor was any different between the Glenmark and the *Mylan*
3 case, correct?

4 A. You're asking me if I don't know that?

5 Q. Right. You don't know --

6 A. I reviewed -- I reviewed the record in Glenmark with
7 regard to inventorship and Dr. Afonso, and I reviewed the
8 record in *Mylan* with regard to Afonso as well. So --

9 Q. And you don't know if there was actually any difference
10 in the factual record with respect to whether Dr. Afonso
11 should have been named an inventor between the Glenmark case
12 and the *Mylan* case, correct?

13 A. My view is that there was a difference.

14 Q. Okay. Well, could we turn to your deposition. It should
15 be one of the spiral-bound binders you have in front of you.

16 A. Yes.

17 Q. You have it?

18 A. Yes.

19 Q. If you will take a look at Page 126 of your deposition
20 starting at line 24 and go to 127, line 17. So 126 starting
21 at line 24. Are you there?

22 A. Yes, I am.

23 Q. Okay. And the question was asked to you, And you don't
24 know if the factual record relating to whether Dr. Afonso
25 should have been named -- should have been an inventor was

1 any different between the Glenmark and *Mylan* cases, right?

2 I'm sorry.

3 A. Where is that?

4 Q. I'm sorry. Let me start again. 126, 24.

5 "And I'm talking about the factual
6 record. Was there any difference in the factual
7 record relating to whether Dr. Afonso should have
8 been named an inventor of Compounds 4E and 4F
9 between the Glenmark case and the *Mylan* case?"

10 "Answer: I don't -- I don't recall
11 addressing that in my report. I haven't really
12 thought about it, if there was -- if there were
13 factual differences with the two cases with regard
14 to what Dr. Afonso did. So I'm not comfortable
15 providing a definitive answer sitting here today."
16 That was your testimony at the time, correct?

17 A. Yes, that was my testimony.

18 THE COURT: What was the date of the deposition?

19 MR. LIVERSIDGE: The date of the deposition was
20 July 1st, 2020, after he had issued all of his opinions in
21 the case.

22 THE COURT: That's almost three years ago?

23 MR. LIVERSIDGE: (Nods head.)

24 THE COURT: Go ahead.

25 BY MR. LIVERSIDGE:

1 Q. Dr. Afonso -- Dr. Hrubiec, all of the events related to
2 Dr. Afonso's work on compounds 4E and 4F were from the 1990s,
3 correct?

4 A. Are we looking at my deposition?

5 Q. No, I'm just asking you.

6 A. Can you repeat the question?

7 Q. Sure. All of the events related to Dr. Afonso's work on
8 Compounds 4E and 4F were from the 1990s, right?

9 A. No, I don't believe that's correct.

10 Q. Okay. Let's turn in your deposition to Page 121, line
11 13, going through 16.

12 THE COURT: If you're trying to impeach him, which
13 it appears that you are, the proper way to do it is to have
14 him look at it, read it, and then ask if that's his
15 testimony.

16 MR. LIVERSIDGE: Thank you, Your Honor.

17 THE COURT: But not for you to read it all into the
18 record.

19 MR. LIVERSIDGE: Just ask if that's what he said?

20 THE COURT: Where are you right now?

21 MR. LIVERSIDGE: I'm at Page 121, line 13.

22 THE COURT: So we are going to go back to 121, line
23 13. How far do you want him to read?

24 MR. LIVERSIDGE: Just 13 to 16.

25 THE COURT: Okay.

1 MR. LIVERSIDGE: So, Your Honor, to be clear, you
2 do not want me to read it into the record?

3 THE COURT: You can. It's just before the Court.
4 So that's fine. Go ahead.

5 BY MR. LIVERSIDGE:

6 Q. "Question: Well, the events related to Dr. Afonso's work
7 on Compounds 4E and 4F took place in the 1990s, correct?

8 "Answer: Correct."

9 That was your testimony, Dr. Hrubiec?

10 A. That's what is written here.

11 Q. Okay. And so the relevant facts on the invention of
12 Compounds 4E and 4F would have occurred before 1994 when the
13 patent application was filed, correct?

14 A. Before 1994, did you say?

15 Q. Yes.

16 A. The relevant facts of the invention, 4E and 4F in this
17 case, would have occurred before the filing in 19 -- I
18 believe it was 1994, yes.

19 Q. Okay. Thank you. You testified a little bit about the
20 re-issue proceedings. Do you recall that?

21 A. No, I don't recall that. Earlier today?

22 Q. Yes, sorry.

23 A. I thought we were in my deposition still. Yes, I recall
24 that.

25 Q. You testified that in the re-issue process, Merck dropped

1 compounds 4E and 4F from the patent. Do you recall that?

2 A. Yes.

3 Q. Now, you understand that in the Glenmark case, Glenmark
4 had an inequitable conduct claim related to Dr. Afonso's
5 claim of inventorship, correct?

6 A. That was one of their claims, correct.

7 THE COURT: And that was one of your claims in
8 where?

9 THE WITNESS: Sorry, ma'am?

10 THE COURT: I'm asking you, Mr. Liversidge.

11 MR. LIVERSIDGE: In the Glenmark case.

12 THE COURT: All right.

13 BY MR. LIVERSIDGE:

14 Q. And also in the *Mylan* case, *Mylan* also had an inequitable
15 conduct claim based on Dr. Afonso's claim of inventorship,
16 correct?

17 A. That was part of their claim, correct.

18 Q. Would you agree, Dr. Afonso (sic), that a re-issue
19 proceeding cannot cure inequitable conduct that occurred in
20 obtaining the patent originally?

21 A. Are you asking Dr. Afonso?

22 MR. LIVERSIDGE: I'm sorry.

23 BY MR. LIVERSIDGE:

24 Q. Dr. Hrubiec, you would agree that a re-issue proceeding
25 cannot cure inequitable conduct that occurred in obtaining

1 the patent originally, correct?

2 A. It cannot cure if there was deceptive intent.

3 THE COURT: The problem I have with this line of
4 questioning, let me just tell you, is that there was a claim
5 of inequitable conduct in the Glenmark litigation, but that
6 claim was never litigated in that litigation because it was
7 settled. Then after it was settled, you got a re-issue,
8 and, yes, the re-issue couldn't cure that, I know that, all
9 right, but you did that because you were coming along with
10 the *Mylan* litigation with the same claim.

11 So I don't understand what connection. Now you
12 want to litigate patent law about re-issue of patents and
13 whether unethical conduct, and maybe later on before Judge
14 Linares it was, but, again, what you're doing here is saying
15 it was a claim in Glenmark. It wasn't litigated. We
16 settled it. You don't know how that claim might have turned
17 out in Glenmark. Then weeks or a short time afterwards, you
18 go in and you apply for a re-issue, and, yes, if it's
19 inequitable conduct, it is not cured by the re-issue.

20 Again, you are trying to use belts and suspenders
21 here that I just am having difficulty seeing the value of
22 the relevance *vis-à-vis* the potential confusion because I
23 have to weigh under Rule 403 the prejudicial effect of the
24 evidence and the confusion that can result versus its
25 potential value and relevance.

1 Again, it's not convincing me, Mr. Liversidge, that
2 because it was later re-issued, that that takes care of what
3 occurred in the Glenmark case. It was never litigated in
4 the Glenmark case. It's after-the-fact action.

5 MR. LIVERSIDGE: Understood, Your Honor. I think
6 the point we are trying to make is that the re-issue didn't
7 change the nature of the inquiry on inventorship for the
8 Court in *Mylan*. It still had to make a determination on
9 whether Dr. Afonso was an inventor of 4E and 4F and had to
10 decide whether he should be named an inventor on the earlier
11 patents. He had to decide all those same issues even though
12 there was a re-issue.

13 THE COURT: They may have been decided differently
14 in the Glenmark case, because you don't know. You didn't
15 complete the litigation. Again, it's an after-the-fact
16 finding that was never determined in the Glenmark litigation
17 when you settled, and that's very important, when you
18 settled it. It was an issue, but it was never determined.
19 I don't know what risk you felt. You must have felt some
20 because you went in and got the patent re-issued.

21 I'm just telling you that it wasn't litigated in
22 the Glenmark case, and now you're trying to go in and say,
23 well, look at what happened after the fact, so that means
24 that everything's okay with us. I'm just having trouble
25 with the logic. I'm not saying ultimately I will, but right

1 now I'm having trouble with the logic here. Go ahead.

2 THE WITNESS: Me, too.

3 BY MR. LIVERSIDGE:

4 Q. Dr. Hrubiec, you testified that there was a change in
5 Merck's expert lineup between the Glenmark and the *Mylan*
6 case, correct?

7 A. Yes, I did.

8 Q. And is it fair to say that you did no assessment of
9 Merck's likelihood of success in the *Mylan* case based on its
10 revised expert lineup?

11 A. I did not provide that opinion, no. I wasn't asked to.

12 Q. You didn't do any assessment of Merck's chances of
13 success in the *Mylan* case, right?

14 A. I did not, no.

15 Q. So you made no assessment to what extent any of the
16 changes that occurred, whether it was experts or counsel or
17 anything, affected Merck's ability to win the *Mylan* case,
18 correct?

19 A. Well, I don't think I needed to assess it. It was
20 already decided on, and Merck won.

21 Q. Right. But you undertook no analysis to assess how any
22 of these changes, among the experts or counsel or anything
23 else, actually impacted Merck's chances of success in *Mylan*,
24 right?

25 A. I looked at it from the standpoint of comparing it to

1 what happened or what was going to happen in the Glenmark
2 case as of 2010, so I could confirm, and confirm to myself,
3 that my opinions in the Glenmark case were solid and didn't
4 need to be changed in any way.

5 Q. Just so I'm clear on your answer, you did not attempt to
6 determine how any of these changes in Merck's case between
7 Glenmark or *Mylan* may have improved or not improved Merck's
8 chances of success in the *Mylan* case, correct?

9 A. I was not looking at the *Mylan* case for that purpose.

10 Q. Okay. You mentioned a change in the law between Glenmark
11 and *Mylan*. Do you recall that?

12 A. Yes, I do.

13 Q. And were you referring to the *Therasense* case?

14 A. At least the *Therasense* case, yes.

15 Q. Do you agree that the *Therasense* decision was irrelevant
16 to an inventorship determination?

17 A. I don't know if I would say it was irrelevant. Perhaps I
18 would put it as perhaps not pertinent to an inventorship
19 determination. The focus of their case, as you know, was
20 with regard to the level of proof needed to show inequitable
21 conduct.

22 Q. Dr. Hrubiec, Dr. Afonso never claimed that he invented
23 the structures of 4E and 4F, correct?

24 A. He did not claim he conceived of the structures of 4E and
25 4F, correct.

1 MR. LIVERSIDGE: Thank you, Dr. Hrubiec.

2 Thank you, Your Honor.

3 MS. KRISTEN JOHNSON: No redirect, Your Honor.

4 Thank you.

5 THE COURT: Thank you.

6 Thank you, Dr. Hrubiec. You may step down.

7 THE WITNESS: Thank you.

8 (Witness excused.)

9 THE COURT: Mr. Liversidge, are you going to
10 examine?

11 Mr. Ismail.

12 MR. ISMAIL: Good afternoon, Your Honor. Tarek
13 Ismail on behalf of the defendants, and we are going to have
14 some binders. Well, just to make sure I have the right
15 stuff here.

16 THE COURT: Got a lot of weekend reading, don't I?

17 MR. ISMAIL: Given the hour I was trying to
18 streamline the presentation. With the Court's permission,
19 Merck would call Mr. Robert Armitage to the stand.

20 THE COURT: That's fine.

21 (Witness was sworn.)

22 MR. ISMAIL: Your Honor, just to give a quick
23 overview of materials provided, we have provided the Court
24 some slides that are some documents that we are going to
25 refer to. We also included the underlying exhibits, to the

1 extent the Court would like to refer to the more fulsome
2 documents in the course of the examination, but to keep
3 things moving, we have the slides so we don't have to flip
4 through as many pages.

5 THE COURT: Thank you.

6 MR. ISMAIL: May I proceed?

7 THE COURT: Yes.

8 MR. ISMAIL: Thank you.

9 ROBERT ARMITAGE, called by the Defendant, having
10 been first duly sworn, was examined and testified as
11 follows:

12 DIRECT EXAMINATION

13 BY MR. ISMAIL:

14 Q. Good afternoon, Mr. Armitage. Can you please state and
15 spell your name for the record.

16 A. Yes. My name is Robert Armitage. The last name is
17 spelled A-r-m-i-t-a-g-e.

18 Q. And, Mr. Armitage, have you been retained by Merck to
19 serve as an expert witness in this matter?

20 A. Yes, I have.

21 Q. And can you please tell the Court on what subjects you
22 were asked to form an opinion?

23 A. I was asked to form an opinion on the prospects for
24 success in the Glenmark litigation we have been discussing
25 and also provide opinions on what a reasonable and competent

1 patent counsel advising either Merck or Glenmark might have
2 advised with respect to the prospects for success in the
3 Glenmark patent challenge, the '721 patent.

4 Q. In the course of your work were you also asked to
5 consider Dr. Hrubiec's opinions and to provide a rebuttal to
6 his stated opinions?

7 A. Yes, I was.

8 Q. Briefly, if you would, Mr. Armitage, would you provide
9 the Court a summary of your educational and professional
10 background?

11 A. Yes. After completing law school, I was -- became a
12 patent trainee for a pharmaceutical company, the Upjohn
13 Company, in Kalamazoo, Michigan where I worked for 20 years.
14 I eventually led the patent group at the Upjohn Company for
15 the last ten years. I was a lawyer in private practice for a
16 half-dozen years. I was a partner in a law firm in
17 Washington, D.C., where I mostly advised pharmaceutical
18 clients on all matter of patent issues, transactional issues,
19 and the like.

20 Ultimately, I concluded my full-time career at Eli
21 Lilly and Company where I was their chief patent counsel for
22 three years, and the last ten years I was at Lilly, I was
23 general counsel and had oversight of the legal group at
24 Lilly, including its global patent operations.

25 For the last ten years, I've served as a consultant

1 in IP strategy and policy matters, and, again, most of the
2 clients I advised are biotechnology or pharmaceutical
3 clients, and my experience ranges from drafting patent
4 applications to prosecuting them to providing advice on
5 patent strategy.

6 Obviously, when I was at Lilly, I was involved in
7 numerous Hatch-Waxman litigations where I was advising
8 management on issues such as prospect for success and
9 opportunities for settlement.

10 Q. In the course of your work to form the opinions that you
11 have disclosed in this case, did you consider and review the
12 underlying patent documents themselves for the '721 patent,
13 the biowrapper as part of your work?

14 A. Yes.

15 Q. Did you also, in the course of your work, consider the
16 materials submitted during the Glenmark patent litigation,
17 including the contentions and arguments of the parties?

18 A. Yes.

19 Q. Did you familiarize yourself with the contentions of the
20 parties in the *Mylan* litigation as well?

21 A. Yes.

22 Q. And you reviewed Dr. Hrubiec's report and his deposition
23 testimony?

24 A. Both his reports and his deposition testimony, yes.

25 Q. Thank you. And you were in court this afternoon

1 listening to Dr. Hrubiec's testimony?

2 A. Yes.

3 Q. Okay. Now, Mr. Armitage, in forming your opinions
4 regarding the strength of Merck's patent and what a
5 reasonable patent lawyer would have advised a client in May
6 of 2010, did you consider the findings made in the *Mylan*
7 litigation?

8 A. Yes.

9 Q. And can you tell the Court, what was the purpose of you
10 looking to the *Mylan* litigation and how that relates to the
11 opinions that you formed in this case?

12 A. Yes. In reviewing the *Mylan* litigation, in my view,
13 there was a common underlying legal issue; namely, the issue
14 of whether Dr. Afonso met the standard for being a joint
15 inventor of the '721 patent, specifically, the joint inventor
16 of claims to compounds E and F as they appeared in that
17 patent.

18 Also, it appeared to me from my review that there
19 were two common underlying factual issues that needed to be
20 determined to assess that common underlying legal issue. In
21 addition, I looked at the role that the judge played in the
22 *Mylan* litigation as in some respects similar to the role I
23 was asked to play; namely, considering all of the evidence
24 that was available to me to reach a determination as to how
25 those factual issues might have been determined and also what

1 the legal consequence was.

2 So ultimately, in my view, because the decision in
3 the *Mylan* case was consistent with the conclusions that I had
4 reached, I found they were confirmatory, at least in my view,
5 of the reliability of the analysis I had made.

6 Q. And we are going to show the Court this afternoon the
7 factual findings that the Court made in the *Mylan* litigation
8 that you found confirmatory of your analysis of the strength
9 of Merck's patents in the Glenmark litigation. Are you
10 prepared to do that this afternoon?

11 A. Yes.

12 THE COURT: Okay. Can you wait just a minute. I
13 want to check something before you go forward. There is a
14 bit of a distinction here because an expert is not a judge.
15 An expert gives an opinion, and a jury is instructed that
16 they are no more bound by the opinion of an expert than any
17 other witness except they must consider the expert's
18 training, background, expertise, and the basis of the
19 opinion.

20 But he is not a judge, and so he's saying that if
21 he were a judge, he would have reached the same conclusion.
22 I think it's more appropriate for an expert to say, this is
23 what I relied upon, and I don't know if what he relies upon
24 is appropriate since there were findings of fact in another
25 case, unless he can say they were the same facts in this

1 case.

2 In other words, he's using the findings of fact of
3 a judge in another case, and experts are not judges, and
4 they can't determine relevance. The Court would determine
5 relevance at a threshold level, and the jury or the trier of
6 fact in the case would then find facts.

7 So I'm not going to nit-pick it at this point, but
8 I would tell you there are problems and certain messages to
9 roles of an expert and roles of finders of the fact, whether
10 it be the judge or the jury and the role of the judge.

11 MR. ISMAIL: Thank you, Your Honor. We will make
12 sure that distinction, if not clear in the question,
13 Mr. Armitage will make clear in his answer.

14 THE COURT: Okay.

15 BY MR. ISMAIL:

16 Q. And just to address the Court's comment, Mr. Armitage,
17 did you view your remit as an expert in this case to give an
18 assessment as to what a reasonable and competent patent
19 lawyer would have advised the parties at the time?

20 A. Yes. Based on my experience doing that over the course
21 of decades, working as a patent attorney and as an executive
22 in-house.

23 Q. And was the *Mylan* record and the outcome of that case
24 part of the materials that you considered in forming your
25 opinions?

1 A. No.

2 Q. Was the conclusions reached in the *Mylan* litigation part
3 of the materials you reviewed?

4 A. Yes, it was.

5 Q. Okay. So let's address a couple of topics that
6 Dr. Hrubiec raised for the Court as distinctions between the
7 *Mylan* case and the Glenmark case, okay. So the first
8 question is that of the re-issue of the '721 patent. You
9 were here to hear Dr. Hrubiec's testimony on that issue?

10 A. Yes.

11 Q. Okay. So how does the '461 patent relate to the '721
12 patent?

13 A. Well, I think as we have been discussing all day, it is,
14 in effect, the replacement for the '721 patent. The '721
15 patent needed to be surrendered for the re-issue patent to
16 issue, and the re-issue patent itself issued with fewer
17 claims and at least one claim that was narrowed.

18 Q. So as the Court has observed in the Glenmark case, the
19 patent at issue was the '721?

20 A. Correct.

21 Q. And in the *Mylan* case, the patent at issue was the
22 reissue '461 patent?

23 A. That's correct.

24 Q. Now, in the Glenmark case did Glenmark make, as one of
25 its defenses, inequitable conduct for improper joint

1 inventorship in that case?

2 A. In the Glenmark case, they -- that is correct. They made
3 an enforceable argument based on inequitable conduct based on
4 improper inventorship.

5 Q. And was that issue presented in the *Mylan* case?

6 A. Yes.

7 Q. And I think, as the Court has observed, by putting the
8 patent into re-issue, did Merck cure the inequitable conduct
9 challenge through the re-issue?

10 A. No. A finding of inequitable conduct in the '721 patent
11 would have had the consequence of being a finding of
12 inequitable conduct in the re-issue.

13 Q. So what did Glenmark and *Mylan* have to prove in order to
14 prevail on its defense that failing to name Dr. Afonso as a
15 joint inventor constituted inequitable conduct?

16 A. Whether -- at least two elements to an inequitable
17 conduct defense. The first is what is known as materiality.
18 In other words, there needs to be an error or omission that
19 was material, and in order for there to be a material error
20 or omission, there would have been a necessary fact finding
21 that Dr. Afonso, in fact, invented Compounds 4E and 4F. And
22 the second prong of inequitable conduct is that error or
23 omission must have been made with the intent to deceive or
24 mislead the patent office.

25 Q. And did Glenmark contend that Dr. Afonso came up with the

1 structures of 4E and 4F?

2 A. No, they did not.

3 Q. Did *Mylan* make that contention?

4 A. No, *Mylan* did not.

5 Q. If Glenmark was not claiming that Dr. Afonso came up with
6 the structures of 4E and 4F, what did Glenmark claim was his
7 contribution?

8 A. Glenmark's contention was that without Dr. Afonso's
9 contribution of an operable method for manufacturing
10 Compounds 4E and 4F, the invention couldn't be completed. In
11 other words, the named inventors otherwise wouldn't have had
12 available to them any operable process for making these two
13 compounds.

14 Q. What argument was *Mylan* making with respect to Dr. Afonso
15 and 4E and 4F?

16 A. *Mylan* was making the identical argument.

17 Q. So let's focus on the first prong that you mentioned,
18 this question about inventorship. Did *Mylan* and Glenmark
19 have the same threshold burden on that question?

20 A. Yes.

21 Q. What are the criteria for being included as a joint
22 inventor on a patent?

23 A. To be included as a joint inventor, you have to make a,
24 what can be called an invented contribution to the conception
25 or the idea of the completed invention, and because these

1 were chemical compounds, you had to visualize or write out on
2 a piece of paper the chemical structure, how the atoms are
3 arranged, and then you need to be able to explain to the
4 public or at least the skilled part of the public how those
5 compounds can be made and used.

6 So you need at least some operable method to exist
7 by which those compounds can actually be made so they can
8 actually be put to some use.

9 Q. And as you mentioned there was no contention in either
10 case that Dr. Afonso conceived of the structures initially
11 and they were focused on the synthesis of 4E and 4F; is that
12 correct?

13 A. Correct.

14 Q. So as to that question that was common between the two
15 cases, what did Glenmark and *Mylan* have to prove in order to
16 show Dr. Afonso invented a compound claimed by Merck's active
17 ingredient patent on Zetia?

18 A. To show Dr. Afonso actually contributed to the conception
19 of Compounds 4E and 4F, you first need to prove that without
20 Dr. Afonso's involvement, the remaining joint inventors would
21 not have had any operable method for making these compounds.

22 The second thing you would need to prove is that the
23 contribution of Dr. Afonso was not just contributing
24 knowledge about the prior art. In other words, he
25 contributed something inventive, over the prior art, such as

1 an inventive process that absent which the remaining
2 inventors would not have been able to explain how the
3 invention could be made.

4 Q. If Dr. Afonso was the first to make 4E and 4F, would that
5 have decided the question about his alleged joint
6 inventorship?

7 A. No, it would not.

8 Q. Was there evidence in -- that you have seen on whether
9 there was known chemistry that could have been used to make
10 Compounds 4E and 4F without the need for undue
11 experimentation?

12 A. There was evidence that without respect to any
13 involvement by Dr. Afonso, the remaining inventors had
14 multiple processes by which known chemistry could have been
15 used to make compounds 4E and 4F.

16 Q. Now, did it matter whether the joint inventors named in
17 the patents actually made Compounds 4E and 4F to the ultimate
18 determination of whether Dr. Afonso should have been named as
19 a joint inventor?

20 A. It doesn't matter whether the compounds were ever made or
21 not.

22 Q. Now, do you recall seeing in the record that Glenmark
23 made the argument that Dr. Rosenblum tried and failed to make
24 4E and 4F?

25 A. I recall that argument.

1 Q. Did *Mylan* make the same argument?

2 A. Yes.

3 Q. Whether or not Dr. Rosenblum made 4E and 4F, does that
4 affect the conclusions you've reached about on the alleged
5 joint inventorship issue?

6 A. It did not.

7 Q. Now let's walk through a couple of places from the
8 Court's opinion.

9 And, Your Honor, I will be referring to the slide
10 deck that have been provided in your binder. But the
11 underlying exhibits are also in your binder as well.

12 So, and do you have a binder up there as well,
13 Mr. Armitage?

14 A. (Nods head.)

15 Q. So let's turn to slide 3, which I think is the second one
16 in your binder. And it says, "Both Glenmark and *Mylan*
17 challenge the '721 patent." Do you see that?

18 A. Yes, I see that.

19 Q. Now, for the Court's benefit, what we are showing here on
20 slide 3 is a portion of the *Mylan* opinion; is that correct?

21 A. Yes.

22 Q. And this is Merck Exhibit 639, Your Honor, also tabbed in
23 the binder. Now earlier you've told us about the fact that
24 there was a second re-issue, that the inventorship challenge
25 was still before the Court in the *Mylan* litigation. Do you

1 recall that testimony?

2 A. Correct.

3 Q. Does the Court's opinion here set forth what patents
4 Judge Linares considered in the *Mylan* case as to the question
5 of Dr. Afonso's alleged inventorship?

6 A. As to the issue of alleged inventorship and, obviously,
7 the issue of inequitable conduct based on that, he's dealing
8 with the predecessor patents, specifically including the '721
9 patent from Glenmark.

10 Q. Okay. So the Exhibit 689 reads, "*Mylan* contends that
11 Dr. Afonso contributed to the conception of four compounds
12 that were named in the '115 and '721 predecessor patents."
13 Are those the patents that were at issue in the Glenmark
14 case?

15 A. Yes. The '721 patent was the patent that Glenmark
16 conceded it infringed.

17 Q. Did Judge Linares make a conclusion as to whether
18 Dr. Afonso was a joint inventor of Compounds 4E and 4F?

19 A. Yes.

20 Q. And I would ask you to turn to slide 4. Is this a
21 portion of the opinion that you reviewed in this case?

22 A. Yes.

23 Q. And did the exhibit -- does it read, "Based on the
24 credible evidence presented at trial, the Court finds that
25 *Mylan* has failed to establish that Dr. Afonso was an inventor

1 of the four compounds at issue that were claimed in the
2 predecessor patents"?

3 A. That's correct.

4 Q. Again, for the benefit of the record, the predecessor
5 patents are which ones?

6 A. They would refer to the '115 and the '721 patents.

7 THE COURT: What was the credible evidence
8 presented at trial? The judge is basing his opinion on the
9 credible evidence presented at trial. Do you know exactly
10 what that evidence is he is basing his opinion on?

11 THE WITNESS: I have not been asked to have
12 rendered any opinion on the admissibility or credibility of
13 evidence at trial.

14 BY MR. ISMAIL:

15 Q. So does the Court set forth the factual determinations
16 that inform the analysis as to whether Dr. Afonso should have
17 been an inventor?

18 A. Yes, he does.

19 Q. And you mention that there were at least two challenges
20 that were facing *Mylan*. Were there other ways to make 4E and
21 4F, and was the method Afonso used inventive, in shorthand,
22 correct?

23 A. Correct.

24 Q. Now, so let's turn, if we could, to the first one of
25 those questions, and that is slide 5. This is Page 27 of

1 Exhibit 739. Again, if you look at the highlighted section,
2 does the exhibit read, "Indeed, it is clear that as of
3 December 1993, the named inventors could have used multiple
4 methods named in this application to synthesize 4E and 4F
5 with routine experimentation. Therefore, Dr. Afonso did not
6 contribute the operative method of making Compounds 4E and 4F
7 to their invention." Did I read that correctly?

8 A. Yes.

9 Q. What is the application being referred to here, in the
10 highlighted section of this opinion?

11 A. This would be the '440 application, which was the
12 immediate predecessor patent to the '721, the immediate
13 predecessor application to the '721 patent -- to the '115
14 patent, sorry.

15 Q. Would this application have been before Judge Linares in
16 the Glenmark case as well?

17 THE COURT: Before Judge Linares in the Glenmark
18 case?

19 MR. ISMAIL: Yes.

20 THE COURT: Judge Linares wasn't trying the
21 Glenmark case.

22 MR. ISMAIL: I'll rephrase. Thank you, Your Honor.

23 BY MR. ISMAIL:

24 Q. Was the '440 application part of the file history for the
25 '721 patent?

1 A. It was part of the overall prosecution history for that
2 patent family, yes.

3 Q. Okay. So the second factual hurdle that you've talked to
4 the Court about is whether the method that Dr. Afonso used to
5 synthesize 4E and 4F, whether that method itself did anything
6 other than apply known chemistry. Do you recall that
7 testimony a moment ago?

8 A. Yes.

9 Q. Was that issue also addressed in the course of the
10 opinion in the *Mylan* case?

11 A. Yes, it was.

12 Q. So I ask you to turn to slide six in your binder. This
13 is Page 23 of Merck Exhibit 639. Does the opinion read,
14 "Even if Dr. Afonso's process was the first operative way to
15 make Compounds 4E and 4F, his process was not novel as it was
16 described in a 1986 paper published in the *Journal of*
17 *Medicinal Chemistry*." Did I read that correctly?

18 A. Yes. Although, it was actually a 1976 paper. That is a
19 typographical error.

20 Q. So what is the significance of this factual determination
21 here that what Dr. Afonso used in the synthesis of these
22 compounds was not novel because it was previously published?

23 A. Yeah. Because in the course of my analysis and also the
24 analysis that was undertaken in the *Mylan* case, this was
25 known chemistry that was used, in effect, that doesn't

1 provide the inventive contribution that one would need to
2 qualify Dr. Afonso to be a joint inventor, even if there
3 weren't multiple other methods that were available for the
4 synthesis of a compound. In other words, there are two
5 hurdles that needed to be met. You had to jump successfully
6 over both hurdles. If you tripped on one, you could not be
7 named as a joint inventor.

8 THE COURT: But you can testify to that
9 independently, can't you? If you are familiar with this
10 paper, then before the testimony goes forward, you just tell
11 a jury, These are the materials that I read, and I
12 determined, this is my expert opinion, and your expert
13 opinion is based upon the underlying documents, not the
14 findings of a finder of fact in an entirely different case
15 that we don't know all of the evidence that was presented.

16 If this is what the judge relied on, and you've
17 reviewed it, then you don't have to say you relied on a
18 judge's finding. You relied on the underlying document. In
19 other words, you even knew that the date was wrong. Isn't
20 that correct?

21 THE WITNESS: Yeah. Just to be very clear, from my
22 point of view, the fact that Judge Linares came to the same
23 conclusion on these two common underlying factual issues
24 actually just confirms the reliability of the opinions that
25 I reached after looking at the evidence that was available

1 in the Glenmark case and that Glenmark had available to
2 submit at trial. I did not rely on this to reach my
3 conclusion as to how a reasonable and competent patent
4 counsel ought to have been advised on the eve of the
5 Glenmark trial.

6 MR. ISMAIL: Thank you.

7 THE COURT: That's very helpful.

8 MR. ISMAIL: Thank you, Your Honor.

9 BY MR. ISMAIL:

10 Q. So just to close the loop on this question about this
11 prior art article cited in the *Mylan* opinion as being an
12 indication that Dr. Afonso didn't do anything inventive in
13 synthesizing the compounds, based on your review of
14 Dr. Brisbois' report in the Glenmark case, was that same
15 article put forth?

16 A. The same article was put forth in the Glenmark case, yes.

17 Q. And was slide 7 in your binder there, which is Merck
18 Exhibit 328, Paragraph 37, is this a portion of
19 Dr. Brisbois's report in the Glenmark patent litigation?

20 A. Yes, with the correct date.

21 Q. Okay. Now, let's just quickly address a couple of other
22 things that Dr. Hrubiec said distinguishes the *Mylan*
23 litigation from the Glenmark litigation, if we could.

24 Did you hear Dr. Hrubiec cite the change in expert
25 lineup between the *Mylan* case and the Glenmark case as a

1 reason to -- that he did not look to the *Mylan* outcome in his
2 opinion?

3 A. I remember -- I obviously heard the testimony, yes.

4 Q. Now, does that argument change your testimony as to how
5 the *Mylan* conclusion is confirmatory of the reliability of
6 your opinions?

7 A. No.

8 Q. And why not?

9 A. Fundamentally, Merck in this case, on this issue of
10 Afonso joint inventorship, had nothing to prove. The burden
11 was entirely on Glenmark to prove that Dr. Afonso made an
12 inventive contribution through clear and convincing evidence,
13 and so the fundamental focus in both cases would have been
14 what evidence did Glenmark have, and, in fact, to some degree
15 Glenmark -- *Mylan* had the advantage of knowing much of what
16 Glenmark might have had in the way of evidence.

17 So from my vantage point, the real reason why there
18 was not a realistic prospect that at trial this issue would
19 succeed is because of the lack of evidence on the part of
20 Glenmark and also the lack of evidence on the part of *Mylan*
21 to meet that evidentiary burden.

22 THE COURT: Where do you get the clear and
23 convincing burden? You are talking about the inequitable
24 conduct burden?

25 THE WITNESS: No. I got the clear and convincing

1 burden because whenever you raise an invalidity defense to a
2 patent, and the Supreme Court recently confirmed that the
3 evidentiary burden is each claim is independently presumed
4 to be valid, and to overcome that presumption of validity
5 for each claim, you require clear and convincing evidence on
6 the factual predicates that would lead to a finding of
7 invalidity.

8 So it's these two factual predicates that needed to
9 be established through clear and convincing evidence.

10 THE COURT: Where does the preponderance of the
11 evidence standard come in?

12 THE WITNESS: On infringement. So, for example,
13 Merck would have had the burden by a preponderance of the
14 evidence to prove that the patent had been infringed.

15 THE COURT: Now we are going to get into burden of
16 proofs in another case. That's really being clear for the
17 jury. I'm being facetious.

18 Go ahead. I mean, to have an expert talking about
19 burdens of clear and convincing and preponderance, that's
20 something that a Court would instruct a jury on based upon
21 the evidence presented and what type of issue, whether
22 you're looking at invalidity, infringement, or whatever.

23 In other words, it's the issue involved, infringing
24 under invalidity, and then it is up to the Court to instruct
25 the jury. Obviously, the Court is a finder of fact knows

1 those burdens, but a jury would have to be instructed on it
2 and understand those burdens and then sort that burden with
3 what their burden was in this case. Is that correct?

4 MR. ISMAIL: So my answer to the question on the
5 burden of proof is the burden of proof on Glenmark to defend
6 the patent litigation in 2010 is relevant to how a
7 reasonable and competent patent lawyer would have advised
8 his or her client at the time.

9 THE COURT: Okay.

10 MR. ISMAIL: And so the heightened burden of proof
11 that faced Glenmark is relevant to their prospects, "their"
12 being Glenmark's prospects of succeeding on their defense.
13 And I believe Mr. Armitage is indicating, it's the same
14 burden that faced both generic companies, *Mylan* and
15 Glenmark. They both had the same burden. So there is not
16 an inconsistency between the two on this question of
17 underlying factual determinations that were being made.

18 THE COURT: What I'm trying to say, the answer
19 would be yes for me. Is that correct?

20 THE WITNESS: Yeah, it -- again, if you go back to
21 what I was asked to do, and if I understood Dr. Hrubiec's
22 testimony, what he was asked to do, this evidentiary burden
23 is inherent in that task of how you would have advised Merck
24 or Glenmark on the prospects for success because any advice
25 would need to account for the clear and convincing evidence

1 burden to succeed on invalidity. And it does help inform
2 the probabilities that you might assign to whether you could
3 successfully meet that burden.

4 THE COURT: Well, Dr. Hrubiec came up with his
5 projections because when the actual information is there
6 from the attorneys that were assessing it, did you have
7 access to the actual lawyers' assessment? In other words,
8 they're Merck's lawyers, and I know it was Schering, so
9 whether they were using that burden or not and what their
10 assessment was, have you seen the attorneys' advice here?

11 THE WITNESS: Yes.

12 THE COURT: You have seen it?

13 THE WITNESS: So from our vantage point, I have no
14 knowledge of any attorney-client privilege communications of
15 Merck involving any aspect of this matter. I was asked to
16 perform what I described mainly, how would I and how would a
17 reasonable and competent patent counsel have advised Merck
18 or Glenmark with the ability to review the materials that
19 I've reviewed, which did not include attorney-client
20 privilege communications.

21 THE COURT: So you would be using this expert to
22 rebut that testimony of Dr. Hrubiec if he testified to that?

23 MR. ISMAIL: Correct. And the construct of the way
24 this question has been framed, there was an early
25 sword/shield privilege challenge, and the way Judge Miller

1 has set the parameters of this is that objective indicia of
2 the strength of the patent and the likelihood of success
3 would be admissible and reliable for the witnesses to refer
4 to.

5 And in Judge Miller's decision on this motion *in*
6 *limine*, he pointed to that same question, is that the
7 conclusions of this fact finder on the same factual
8 predicate questions is objective evidence of how a client
9 would be advised about the prospects of success. So it's
10 specifically relevant to the inquiry and the reliability of
11 Dr. Hrubiec's opinion that -- there is an objective
12 determination that Dr. Afonso did not contribute inventive
13 efforts to 4E and 4F, which was an issue in the Glenmark
14 litigation and was an issue in the *Mylan* litigation.

15 And so that's what we believe to be one of the
16 reasons why the *Mylan* outcome is relevant, in addition to
17 the many other reasons Mr. Liversidge outlined this
18 afternoon. I hope that answered the Court's question, and
19 then some probably.

20 THE COURT: Go ahead.

21 MR. ISMAIL: Thank you, Your Honor.

22 BY MR. ISMAIL:

23 Q. Just a couple of other quick points, Mr. Armitage, if I
24 could. So were you here when counsel for the plaintiffs and
25 Dr. Hrubiec were talking about a supposed change in Merck's

1 theory as to the inventors of 4E and 4F?

2 A. Yes.

3 Q. Okay. So does the distinction about who conceived of the
4 structures 4E and 4F change your opinion as to whether
5 Dr. Afonso should have been an inventor on the predecessor
6 patents?

7 A. So long as the named joint inventors were responsible for
8 that part of the conception, whoever they were of the
9 structures, it doesn't matter at all to the analysis of
10 Dr. Afonso's joint inventorship. It's simply irrelevant.

11 Q. So if Dr. Rosenblum conceived of the structures 4E and
12 4F, is that a fact whether Dr. Afonso would be considered a
13 joint inventor?

14 A. As opposed to Dr. Burnett and Dr. Clader, no.

15 Q. And did -- on this question about whether Dr. Afonso was
16 the first to synthesize 4E and 4F, was that issue addressed
17 in Judge Linares' opinion?

18 A. Yes.

19 Q. And if we go to slide 8, and would this be Page 27 of
20 Merck Exhibit 639, does it read, "Whether Dr. Afonso was the
21 first or second person to actually synthesize Compounds 4E
22 and 4F makes no difference because reducing the compound to
23 practice does not make a person an inventor." Is that
24 consistent with your analysis in this case?

25 A. In this case it is consistent.

Armitage, R. - Direct

110

1 THE COURT: Would it be inconsistent in another
2 case?

3 THE WITNESS: There is a bizarre doctrine that
4 applies to some obscure types of invention called
5 simultaneously conception and reduction to practice, but
6 that has no conceivable relevance here.

7 THE COURT: All right.

8 BY MR. ISMAIL:

9 Q. Okay. So let's just wrap this up, Mr. Armitage, and late
10 on a Friday afternoon. So in the final analysis, did
11 Glenmark and *Mylan* face similar factual hurdles to establish
12 an inequitable conduct defense based on joint inventorship?

13 A. They based what I would say would be common factual
14 hurdles.

15 Q. And did you reach an opinion as to the likelihood or how
16 you would have advised a client in 2010 as to Glenmark's
17 prospects of overcoming those factual hurdles?

18 A. Yes.

19 Q. And in Judge Linares's opinion in the *Mylan* case, did he
20 assess whether *Mylan* was able to overcome those common
21 factual hurdles?

22 THE COURT: Are you asking him how he would assess
23 Glenmark's, is that the question?

24 MR. ISMAIL: I'll rephrase to make it clear.

25 BY MR. ISMAIL:

1 Q. Were you asked to assess how you would advise a client as
2 to the prospects of Glenmark successfully clearing the
3 hurdles necessary to establish the inequitable conduct
4 defense on joint inventorship?

5 A. Yes.

6 Q. And did the *Mylan* opinion have an analysis of whether
7 *Mylan* was able to clear those common factual questions?

8 A. Yes.

9 Q. And do you, Mr. Hrubiec, find -- and I think you
10 indicated that the opinion and findings in the *Mylan* case
11 were confirmatory of the work that you did to arrive at the
12 opinions that you've provided the Court today?

13 A. In my view, they confirm the reliability of the analysis
14 and the conclusions.

15 MR. ISMAIL: Thank you, Your Honor. Pass the
16 witness.

17 THE COURT: Cross-examination, Mr. Sobol.

18 MR. SOBOL: May I inquire, Your Honor?

19 THE COURT: Yes.

20 CROSS-EXAMINATION

21 BY MR. SOBOL:

22 Q. Good afternoon, sir.

23 A. Good afternoon.

24 Q. We haven't met before, so I'm Tom Sobol. I'll be asking
25 you some questions this afternoon, okay? You just gave some

1 testimony -- used this word "confirmatory." I take it that
2 your testimony is that the *Mylan* result is confirmatory of
3 your findings, I think you testified; is that correct?

4 A. I think I said confirmatory of the reliability of the
5 conclusions I reached.

6 Q. Okay. So it confirms your conclusions, correct?

7 A. In both cases the same ultimate conclusions were reached,
8 yes.

9 Q. Right. But what I'm trying to understand is you reached
10 your conclusions independently of relying upon the *Mylan*
11 results, correct?

12 A. Correct.

13 Q. And so you don't need the *Mylan* result in order to reach
14 your opinion, correct?

15 A. Correct.

16 Q. The only thing you need to do is get your opinion
17 confirmed with *Mylan*, correct?

18 A. No, that wasn't my testimony. I think I said confirm the
19 reliability of the opinion that I reached.

20 Q. Okay. So the underlying opinion that you reached, it is
21 reliable independent of *Mylan*, isn't it, in your view?

22 A. If my view it's the type of opinion that if I provided to
23 the board of directors of the CEO of a company, they should
24 rely on it, yes.

25 Q. So be the kind of opinion that reasonable and competent

1 count -- strike that. Let me make sure it's clear. Putting
2 aside any utility, any use of the *Mylan* result, it's your
3 view that your underlying conclusions about the likelihood in
4 the Merck-Glenmark case are adequate for the purposes of
5 advising people in the position of Merck or Glenmark, right?

6 A. I think they are at least adequate, yes.

7 Q. So you don't need to get into *Mylan* in order to testify
8 to the jury about your opinion on the strengths and
9 weaknesses of the Glenmark case?

10 A. Well, I would disagree to the extent that *Mylan* is
11 available. I would be able to testify to the jury as to the
12 outcome in *Mylan*, the common factual issues in *Mylan* in a
13 manner in which *Mylan* was confirmatory of the reliability of
14 my opinion --

15 Q. Sure.

16 A. -- if permitted.

17 Q. I'm sorry. I didn't mean to interrupt.

18 THE COURT: Excuse me for a minute. But ultimately
19 you make the opinion, and then the jury determines whether
20 it's reliable or not. In other words, an expert makes an
21 opinion and says the reasons for it, but you don't testify
22 that your opinion is confirmed by someone else's opinion, a
23 judge's? In other words, you make an opinion based upon
24 certain sources, and you're saying that you can make those
25 opinions separate from *Mylan*, and then you give those to a

1 jury, and the jury determines its reliability or whoever's
2 the trier of fact? So why would you need the *Mylan* opinion?

3 THE WITNESS: When you say why would I need the
4 *Mylan* opinion, I did not need the *Mylan* opinion to reach the
5 conclusions that I reached, and I don't want to keep
6 repeating myself, but having reviewed the *Mylan* opinion, the
7 common underlying legal issue, the common underlying factual
8 issues, the *Mylan* opinion is, in fact, confirmatory of what
9 I regard as the reliability -- I might even use the word
10 credibility, of my opinion.

11 In other words, it is my opinion, but -- well, it
12 is my opinion without the *Mylan* opinion ever having been
13 rendered. With the *Mylan* opinion having been rendered, at
14 least my view is that it does confirm its reliability.

15 BY MR. SOBOL:

16 Q. So if I understand the answer you just gave then, you'd
17 like to bolster your credibility in front of the jury by
18 putting before the jury the full decision of a federal court
19 judge from the *Mylan* case as confirming your opinion? That's
20 what you want to do?

21 A. No, that's not what I said and not what I want to do.
22 It's not my credibility. It's not my reliability. It's the
23 reliability of the conclusions that I reached.

24 Q. But in order to affirm the reliability of your opinion,
25 it's your expectation that you would be put before -- when

1 you testify before the jury, that Merck's trial Exhibit
2 MDX639, the decision of Judge Linares in the *Mylan* case,
3 would go in evidence in order to confirm your opinions?

4 THE COURT: Who says that's going to be a trial
5 exhibit?

6 MR. SOBOL: It's marked as Merck's trial exhibit.

7 THE COURT: There is an objection to it, isn't it?

8 MR. SOBOL: Absolutely, yes.

9 THE COURT: So it's not determined yet that it's
10 going to be an exhibit because I haven't ruled on the
11 objection, but you can say assuming it's an exhibit. I just
12 want this record to be clear that I have not agreed, and I
13 have not ruled on that objection. I have reviewed the final
14 pretrial order, which was just entered this morning in that
15 regard, but, in any event, it's not in evidence, but you can
16 assume it for purposes of your examination.

17 MR. SOBOL: That's correct. I should have said
18 proposed Merck Exhibit 639.

19 BY MR. SOBOL:

20 Q. It's your understanding that proposed -- Merck proposes
21 to put in evidence the full decision of the *Mylan* court? You
22 understand that, correct?

23 A. If you represent that to me, I certainly understand it,
24 yes.

25 Q. Now, I also understand that you did not have access to

1 any of the attorney-client privileged communications that
2 Glenmark had with its lawyers in the Glenmark case and that
3 Merck had with Merck's lawyers in the Glenmark case, correct?

4 A. Correct.

5 Q. Okay. If I understand it correctly, you've been -- I
6 tried to add up the years that you have been doing patent
7 law. You have been doing patent law for a long period of
8 time, correct?

9 A. Yes.

10 Q. And, by the way, I didn't mean any offense by that. I
11 did not.

12 THE COURT: Age is an advantage to wisdom.

13 BY MR. SOBOL:

14 Q. And if I understand it, you've had the handicap what's
15 going to happen in litigation before?

16 A. I have done that before on numerous occasions.

17 Q. Right. And when -- in litigation, if one side is saying
18 something like Afonso was the inventor, sometimes in
19 litigation you might want to say Afonso didn't do it, this
20 other person did, just in terms of trying to make sure that
21 you can persuade the finder of fact that Afonso is not the
22 inventor, this other person is? You would expect somebody to
23 do that, right?

24 A. I respectfully don't understand the question. I
25 apologize.

1 Q. Okay. Well, let me put it in the context of this case.
2 In the Glenmark case, for whatever reason, the Glenmark
3 lawyers were arguing that Afonso didn't invent 4E and 4F,
4 Rosenblum did. You understand that?

5 A. No. Technically, no, I do not understand that.

6 Q. Sorry, had a method to make -- I misspoke somewhere
7 there. Let me put this again. Okay. In the Glenmark case,
8 Glenmark took the position that Rosenblum -- no.

9 MR. SOBOL: I've got this wrong. Now I understand
10 what I'm doing wrong. It has been a long afternoon. What I
11 should be doing is my left hand and my right hand.

12 BY MR. SOBOL:

13 Q. In the Glenmark case, Merck took the position -- I have
14 to start this again.

15 THE COURT: What you're asking is in the Glenmark
16 case, what the position of Merck was in regard to --

17 BY MR. SOBOL:

18 Q. Right. In regard to who made 4E and 4F, do you know?
19 Let me go to the documents to help me out here. Let me take
20 a step back from that, okay. So we know that Merck sought
21 re-issue four weeks or so after it settled the Glenmark case,
22 right?

23 A. Correct.

24 Q. Companies usually seek re-issue in order to improve their
25 position, not make their position worse, correct?

1 A. That can be one reason, yes.

2 Q. Right. We don't know the reasons exactly why Merck did
3 so here because it has claimed attorney-client privilege even
4 as to the re-issue also, you understand that?

5 A. Yes.

6 Q. Okay. But for whatever reason, presumably in order to
7 advantage Merck's position, it sought re-issue, correct?

8 A. Well, when you say presumably, that's certainly a
9 possibility. It's not a presumption I've made one way or the
10 other.

11 Q. All right. And then when it surrendered that patent and
12 the patent that ends up being litigated is now the '641,
13 correct, rather than the prior patent, right?

14 A. That's correct. The number changes.

15 Q. Okay. And do we know in any way how Merck thought it had
16 improved its position by doing that?

17 A. The only thing I know is what Merck stated in the
18 re-issue papers.

19 Q. Right. And what Merck stated in the re-issue papers was
20 that the patent wasn't -- the '721 patent was invalid in
21 whole or in part because it had -- because the patentee had
22 claimed more than it was entitled to, correct?

23 A. If I recall correctly, what Merck claimed is that it was
24 removing certain subject matter of the claims to avoid an
25 issue of potential inherent anticipation, which is another

1 exotic doctrine of patent law, and, therefore, in order to do
2 that they needed to file a re-issue oath which made an
3 admission to that effect in order to allow the patent office
4 then to grant the narrow claims, the claims they canceled and
5 the claims they amended to narrow them.

6 Q. Okay. Now, I can go back to where I was before. If you
7 can turn to Tab 6, please. This is a photocopy of Merck's,
8 Schering's pretrial brief in Glenmark, correct?

9 A. That is certainly what it appears to be.

10 Q. Okay. And please turn to Page 9.

11 A. I'm there.

12 Q. On Page 9 Merck takes the position that the structure for
13 both compounds, meaning 4E and 4F, the structure for both
14 compounds was first conceived by inventor Rosenblum, that's
15 what position that they took, correct?

16 A. I'm sorry. I'm on the wrong 9. I see that line is
17 highlighted there.

18 Q. Right. You knew about that before here today, right?
19 You knew that in Glenmark Merck took the position that it was
20 Rosenblum who conceived of 4E and 4F?

21 A. My understanding is actually that in the trial order that
22 came after this, that there was no contention by Merck that
23 Rosenblum had conceived Compounds 4E and 4F, so had the case
24 gone to trial, it wouldn't have gone to trial with any
25 contention that it was Rosenblum who had done that.

1 Q. I see. And so Merck had to shift its position during the
2 litigation?

3 A. I'm not so sure that there was a shift in position here.
4 I actually don't know exactly what happened. But in
5 reviewing all of the documents, it appears to me that, as I
6 testified earlier, it didn't make any difference which of the
7 main joint inventors did from the standpoint of trying to
8 prove Afonso was necessarily a joint inventor.

9 Q. Sure. I understand that your testimony is you want to
10 focus only on the Afonso side of this discussion, but for
11 whatever reasons, Merck thought it important in its pretrial
12 brief to say that it was Rosenblum who first conceived of 4E
13 and 4F?

14 A. Well, as far as I know, and basically I have no insight
15 into any attorney-client privilege communications, this just
16 looks like it could possibly be an error that wasn't
17 uncovered when this trial brief was filed, which is why the
18 pretrial order is different.

19 Q. Okay. And then if you turn to tab 7, do you know what
20 position Merck took in the *Mylan* case regarding who conceived
21 of 4E and 4F?

22 THE COURT: Where are we now?

23 MR. SOBOL: If you turn to tab 7.

24 THE COURT: I'm sorry tab, 7.

25 BY MR. SOBOL:

1 Q. Tab 7 is the joint submission of the parties in the *Mylan*
2 case of proposed findings of fact. Are you with that tab,
3 sir?

4 A. Yes.

5 Q. And is this something that you reviewed in connection
6 with your report and testimony?

7 A. This is probably something I reviewed in the year 2020,
8 but, yes.

9 Q. And then if you turn to Page 37 of these proposed
10 findings, you will see there a heading A, "Conception of
11 synthesis of compounds 4E and 4F."

12 A. Yes.

13 Q. And then there is over -- so the way this is set up is on
14 the left side is *Mylan's* proposed findings and on the
15 right-hand side is Merck's proposed findings. That's the way
16 they set this up here, okay?

17 THE COURT: I'm in tab 7 and what page?

18 MR. SOBOL: 37, Your Honor.

19 THE COURT: Is there a Bates number at the bottom?

20 MR. SOBOL: Yes. It ends in 096.

21 THE COURT: That helps me. It's a thick document.
22 I'm there.

23 BY MR. SOBOL:

24 Q. So if we turn to this page, this is in the *Mylan* case,
25 the *Mylan's* proposed findings are on the left and Merck's on

1 the right, correct?

2 A. Correct.

3 Q. Okay. And then this is under the heading of "Conception
4 and synthesis of Compounds 4E and 4F," correct?

5 A. Correct.

6 Q. Okay. Now, then if you look at Paragraph 122, now Merck
7 is taking the following position: "The structure of
8 Compounds 4E and 4F was conceived by Clader and Burnett. The
9 structure is shown on Schering documents." And then it says,
10 "At the time neither Rosenblum nor Afonso was yet involved in
11 the project." That's the position they took then, right?

12 A. Yes. That would appear to be the position consistent
13 with the documents I reviewed in connection with the Glenmark
14 litigation.

15 Q. And then if you also go back to the Glenmark litigation
16 for a moment, it was the method that Afonso -- excuse me,
17 that Rosenblum said that he had that Merck put forward as the
18 basis of invention, correct? If you turn back to tab 6, Page
19 9 -- excuse me, tab 6, Page 10.

20 A. I'm sorry. You're on tab?

21 Q. Tab 6, going back to Glenmark. See how easy this will be
22 for the jury, too. Turn back to Tab 6, Page 10, please.

23 A. Yes.

24 Q. Okay. At the paragraph that begins, "Glenmark's
25 argument." Then it says, "To start with, when Rosenblum

1 conceived of the structure of Compounds 4E and 4F, he had a
2 method in mind to make them. He described the method in his
3 lab book and carried it out. His method works." Then the
4 last sentence -- second to last sentence here, "Under the
5 law, so long as Rosenblum had an operative method to make
6 Compounds 4E and 4F, he was the sole inventor of those
7 compounds." That was the position taken by Merck at this
8 time, correct?

9 A. That's correct.

10 Q. So it wasn't a typo or a mistake on the prior page when
11 they had attributed conception to Rosenblum. Here they are
12 saying now he is the sole inventor of 4E and 4F? Right?

13 A. Again, I don't want to get into exotic areas of patent
14 law but --

15 Q. Nor do I.

16 A. -- it's possible that this could be true and irrelevant
17 at the same time. But, in any case, I would not disagree
18 with you. There is a slight difference. The first
19 contention on Page 9 was that it was first conceived by
20 Rosenblum. That's clearly wrong. However, if Rosenblum
21 conceived of the structure and operable way to make it, he
22 could be the sole inventor. He would not be the first
23 inventor, and, therefore, under the applicable patent law at
24 the time, you would not name him as the sole inventor, but
25 it's all irrelevant since he would have been, in any event, a

1 joint inventor with other joint inventors on the patent.

2 Q. Okay. Thank you. Now, I take it if we -- take a step
3 back from this comparison for a moment. The Glenmark settles
4 the -- the Glenmark case settles in May of 2010, correct?

5 A. Correct.

6 Q. And then the Glenmark -- excuse me, the Mylan case is now
7 continuing on for a year or more to trial, correct?

8 A. Correct.

9 Q. Now, during that period of time, what do you think a
10 reasonable and competent patent counsel at Merck were doing
11 with respect to the *Mylan* case? Shall I reframe?

12 THE COURT: He didn't say he didn't understand it.
13 I understood the question. Did you understand it,
14 Mr. Armitage?

15 THE WITNESS: Yes, I did. Again, I don't know at
16 what point it became clear that *Mylan* would focus solely on
17 the issue of the inventorship of Dr. Afonso. But as I
18 explained in my expert report, by the time the Glenmark
19 trial, Merck's lawyers would have been ready to go with the
20 entire case. And so the only possibility is they would
21 continue to do some additional work. Dr. Hrubiec suggests
22 they may have changed experts, et cetera, and they would
23 have continued on on the assumption that the war is not over
24 until the *Mylan* case finally is decided.

25 THE COURT: Wait. Now I'm not clear on that

1 answer. The Glenmark case, they had gotten all the way up
2 to a final pretrial order.

3 THE WITNESS: The Glenmark case was settled as the
4 case was about to go to trial.

5 THE COURT: Exactly.

6 THE WITNESS: So at that time the trial
7 preparations for Merck, to do whatever it needed to do to
8 defend its patents, would have been complete, and, you
9 know -- you asked me what a reasonable and competent patent
10 counsel could have done. One is, we will just wait and try
11 the same case as *Mylan*. The other is, as Dr. Hrubiec
12 suggested, make some changes in the expert lineup.

13 THE COURT: But the Glenmark case, when it settled,
14 was basically ready to go, the discovery was over, and you
15 are saying that then they settled on the basis of keeping
16 *Mylan* going?

17 THE WITNESS: So having been involved in many of
18 these, when you have multiple Hatch-Waxman litigations, and
19 I had this when I was at Lilly, you do not win until you've
20 won against each of the generics bringing the challenge. So
21 settling with Glenmark did nothing to eliminate the risk of
22 early generic competition because there was going to be a
23 trial in *Mylan*, and that would determine the outcome of
24 exclusivity for the Ezetimibe products.

25 THE COURT: Go ahead.

1 BY MR. SOBOL:

2 Q. One hypothesis might be that reasonable and competent
3 patent counsel, after settling Glenmark, wouldn't just sit on
4 their hands, but they would try to improve the case as they
5 go ahead with *Mylan*, correct?

6 A. Yes.

7 Q. Okay. And so, for instance, we know from the patent
8 record that Mr. Roush, he originally had a 111-page report,
9 and then he changed to had a new report at about 140 pages in
10 it. You know that, right?

11 A. I've not done the page counting, but I will take your
12 representation.

13 Q. Right. And then there was also another new expert that
14 came into a part of the picture, this Dr. Myers, correct?

15 A. As I understand Dr. Hrubiec's testimony, we agree on
16 that.

17 Q. In the Glenmark case, what did Glenmark say Afonso
18 invented?

19 A. In the Glenmark case, as in the *Mylan* case, the
20 allegation was that Afonso contributed to the conception of
21 Compounds E and F.

22 Q. Right. What did *Mylan* say that Afonso invented in the
23 *Mylan* case?

24 A. The identical 4E and 4F contributed to the conception of
25 the invention, and then *Mylan* additionally tried to prove

1 that Dr. Afonso contributed to other subject matter which
2 wouldn't have been relevant to the Glenmark case.

3 Q. Well, in *Mylan*, *Mylan* took the position that Afonso
4 invented Zetia, Ezetimibe, in addition to the two compounds
5 that they had said they invented in Glenmark, correct?
6 That's the new subject matter you are talking about?

7 A. Yes, but that wasn't actually of any relevance to the
8 cast I had in Glenmark. In other words, because they were
9 seeking a common underlying issue of Compounds 4E and 4F, it
10 wasn't necessary for me to look at the merits in the *Mylan*
11 case of the rest of the allegations that *Mylan's* attempting
12 to prove.

13 Q. But you do know that the *Mylan* court, Judge Linares,
14 has -- a large part of his decision is knocking down the
15 notion that Afonso was the inventor of Ezetimibe, correct?

16 A. Correct.

17 Q. So let's just look to -- if you go to tab 15, please.
18 Tab 15 is a photocopy of the decision of the *Mylan* District
19 Court, right?

20 A. It appears to be, yes.

21 Q. You turn to -- stay with tab 15 but go to Page 15,
22 please. During the course of the *Mylan* Court's decision, the
23 Court observed that Schering -- Ms. Russell -- it says here
24 the following, "According to Schering, Russell's" -- that
25 is the IP head at Schering at the time, correct, the senior

1 IP lawyer at Schering, Russell?

2 A. He was legal director of patents.

3 Q. Okay. "According to Schering, Russell's concerns about
4 the potential invalidity of the '721 patent claims were based
5 on earlier litigation with Glenmark. Glenmark argued that
6 certain claims were invalid due to inherent anticipation."

7 That's what the Court wrote, correct?

8 A. Yes.

9 Q. So that's part of the background. Then also the Court
10 provides -- if you turn to the next page, please -- provides
11 more remarks regarding what the re-issue was and how the
12 re-issue was arose because of things that were learned during
13 the Glenmark litigation, correct?

14 A. Correct.

15 Q. Okay. Then on Page 17, Judge Linares makes some
16 observation that there was testimony before him about this
17 experiment that this guy, Mr. Brisbois made, in order to
18 confirm Rosenblum's ability to synthesize 4E and 4F, makes
19 some observations about it, correct?

20 A. Correct.

21 Q. And then there is a section that begins at Page 21, it's
22 a discussion, and then there is a discussion -- see III on
23 Page 21, sir?

24 A. Yes.

25 Q. Then A, and then the discussion that the Court has here

1 on these pages reaches the conclusion, if you will, that
2 Afonso did not invent Ezetimibe?

3 (Pause)

4 So this section here, the section under inventorship,
5 I thought you were looking over this, Mr. Armitage. This
6 section reaches the conclusion that Dr. Afonso did not invent
7 Ezetimibe also, is it fair to say?

8 A. I believe that's correct, yes.

9 Q. Sorry, everybody.

10 A. I apologize for the silence. I was waiting for the
11 question.

12 Q. I was trying to be polite, so I'm sorry. I'm going to
13 move this along. So now there on Page 25 we finally get to
14 the inequitable conduct section of the decision, correct?

15 A. The heading is labeled "Inequitable conduct," but the
16 inventorship predicate we have been talking about is actually
17 the materiality aspect of inequitable conduct.

18 Q. Buried in here, yes. If we turn to Page 27, please.
19 Further, it says, the following, "Further, with respect to
20 Compounds 4E and 4F, *Mylan* failed to prove that Dr. Afonso
21 made a contribution to invention of this compounds beyond
22 their first synthesis." So that's the conclusion that the
23 Court makes, correct?

24 A. Correct.

25 Q. Now we are going to get the reasons for that conclusion.

1 "Rather, the evidence at trial suggests that these compounds
2 were first conceived by Drs. Burnett and Clader as
3 demonstrated by the '440 application." That's the first
4 reason he gives, correct?

5 A. It's the first reason stated here, yes.

6 Q. Yes. And then he -- and that was, by the way, as I
7 showed you before, one of the findings of fact that Merck had
8 put forward, that it was Burnett and Clader who had first
9 conceived of Compounds 4E and 4F?

10 A. That's correct.

11 Q. And then the next sentence says, "In fact, according to
12 Professor Roush, if a chemist had been able to make Compound
13 8F, as Dr. Burnett had done, that chemist would have also
14 been able to make Compounds 4E and 4F after routine
15 experimentation." That was also his reason, correct?

16 A. That's correct.

17 Q. Not, by the way, that Rosenblum had a method of his own
18 to make it and was successful in doing that, that's not the
19 reasons being given here?

20 A. Well, this is, as I understand compound 8F, this compound
21 was made in a prior patent that was prior art, which was also
22 prior art considered in Glenmark.

23 Q. Right. And here, though, there is no rational -- so, by
24 the way, here the Court does not rely at all, the Court, the
25 *Mylan* court, does not rely at all upon the evidence of

1 Brisbois's experimentation to confirm Rosenblum's ability to
2 make 4E and 4F, correct? There is no reliance by the Court
3 at all?

4 A. That is not correct. There is another portion of this
5 decision that references -- in fact, it says it is clear
6 there were multiple methods that could have been used to make
7 these compounds, and one of the multiple methods was the
8 Brisbois method. Other methods were actually methods
9 described in Glenmark's own expert's report. So it is sort
10 of the full answer to that question requires that context.

11 THE COURT: So, in other words, a jury would have
12 to understand prior art, and these are all patent concepts,
13 not antitrust concepts. So a jury would have to understand
14 prior art. I understand prior art. Number of patent cases.
15 And they would have to understand methods, and the
16 particular meaning that method has in patent law.

17 So they would have to have pretty much an education
18 in patent law in order to understand some of the reasonings
19 here that Judge Linares, since it was a patent case before
20 him, would have to have understand as a judge and as a bench
21 trial?

22 THE WITNESS: All of that they would need to
23 understand in order to evaluate either Dr. Hrubiec's
24 opinions or my opinions because we are both basing our
25 opinions on facts in evidence that was available at the time

1 the Glenmark case was prepared to go to trial, which
2 included all of this information, and the reference here is
3 to the '440 application.

4 There is also a reference here to Compound 8F,
5 which was a compound that could be made by a prior art
6 method, which means that if that method was useful for
7 making Compounds 4E and 4F, it automatically would have
8 disqualified Dr. -- I'm sorry Dr. Afonso from being a joint
9 inventor.

10 So irrespective of what's in the *Mylan* opinion,
11 these are all the issues the jury is going to have to tackle
12 if it's going to assess what a reasonable and competent
13 patent counsel would have advised Merck and Glenmark as to
14 the likelihood of success.

15 THE COURT: So even though it's an antitrust case,
16 and it centers around the settlement of the case, where
17 these issues didn't finally resolve itself, you are saying
18 we would have to have a mini patent trial here and then move
19 into an antitrust case?

20 THE WITNESS: Is that a question for me?

21 THE COURT: It is a question for you, sir.

22 THE WITNESS: In -- I've only had limited
23 involvement, but I have had some involvement in antitrust
24 trials based on patent issues, and that's fundamentally
25 exactly how the trial proceeds.

1 In other words, the jury hears evidence typically
2 from patent experts about the legal issues, and here the
3 legal issues is going to relate to the -- what a reasonable
4 and competent patent counsel would have advised its
5 likelihood of success, and in order to get into that issue,
6 you have to understand the law in inventorship, what you
7 need to prove to be a joint -- be a joint inventor, which
8 would require understanding, you know, this idea of what
9 conception is and the relevance of a way to make it, and
10 basically go through the analysis that I certainly did in my
11 expert report.

12 It's the type of analysis that was actually done in
13 Judge Linares's decision in *Mylan*, and that's how you reach
14 a conclusion about the likelihood that that type of defense
15 would be able to prevail. And obviously Dr. Hrubiec and I
16 have different views on that. I stated in my expert report
17 the basis for my views.

18 THE COURT: All right. But you don't have to go
19 through all of that if you have the attorneys, if you have
20 what the attorneys were advising at the time? I mean, they
21 settled it. They settled the case. They settled it on
22 attorney advice. Nobody is going to settle a case that big
23 except on attorney advice. You've got the attorney advice,
24 it's just we can't get to it. I'm just making a comment on
25 the record. So perhaps the jury is going to need to know

1 that while you have an attorney-client privilege, and you're
2 entitled to assert it, that you have asserted it, so,
3 consequently, that's why we have these projections and all
4 of this testimony, because you've got a privilege, and
5 you're certainly entitled to assert it, and the jury would
6 know that, but they may wonder why they are hearing all of
7 this testimony about another case. Just a comment, not a
8 ruling.

9 Okay. Go ahead.

10 BY MR. SOBOL:

11 Q. So to whatever extent in the antitrust trial we get into
12 the issues of handicapping a Merck versus Glenmark
13 litigation, which is I think in part what you are telling me
14 about it, you are saying we will have to get in some notion
15 of patent issues with respect to Merck versus Glenmark, is
16 that fair to say, what you were answering to the Court a few
17 moments ago?

18 A. When you say, "Some notion," at least as I understand the
19 pleadings in this case, you need more than some notion.

20 Q. Well, fair enough. To the extent that we get into patent
21 issues with Merck and Glenmark -- let me put the question
22 this way. To the extent that we get into issues with respect
23 to handicapping the Merck versus Glenmark case, if we get
24 into this *Mylan* issue, then we have to also start getting
25 into issues of handicapping that case, too, correct?

1 A. No. Because that case was decided, and as I say, and I
2 said several times, I did not rely on that except to confirm
3 the reliability of the opinion I reached based on the
4 underlying work that I had done.

5 Q. Sure. Thank you. Let me wrap up with this couple of
6 questions, sir. You have been practicing patent law for
7 decades, fair to say?

8 A. Yes.

9 Q. Okay. And you've got hundreds of hours into this case or
10 at least more than a hundred hours into this case, correct?

11 A. Undoubtedly.

12 Q. And preparing for your testimony for today, what would
13 you give as a ballpark of the amount of time you've spent
14 preparing?

15 A. I spent two days in Florida before I came up here and
16 last evening and sometime this morning.

17 Q. And the only issue that we were talking about for all of
18 that preparation was how you were going to answer questions
19 here today on the comparison of Glenmark case to the *Mylan*
20 case?

21 A. Well, if the issue is the only preparation that I did
22 related to the subject matter of this hearing, the answer is
23 yes.

24 MR. SOBOL: Nothing further, Your Honor.

25 THE COURT: All right. Redirect.

1 MR. ISMAIL: No, Your Honor. Thank you.

2 THE COURT: Mr. Ismail, if you can come to the
3 podium, I have a couple of questions.

4 Thank you very much, Mr. Armitage. You are
5 excused.

6 (Witness excused.)

7 THE COURT: Mr. Ismail, it would be helpful to the
8 Court if you can identify the witnesses that you intend to
9 introduce evidence of the *Mylan* case through and for what
10 purposes. I want to know the ones that you plan on for
11 impeachment and the ones that you plan on for substantive.
12 Depending upon how I rule, unless the door is opened, you're
13 only looking at impeachment witnesses.

14 MR. ISMAIL: Correct. So just so I'm clear with
15 the Court's question, plaintiffs' witnesses, for whom we
16 believe the *Mylan* evidence is relevant, is that part of your
17 question, our witnesses?

18 THE COURT: It would be helpful to the Court. What
19 are your intending to do? If a witness is impeachment,
20 that's one thing. If a witness is substantive, then you're
21 creating a whole additional issue if they haven't opened the
22 door. So what I'm asking you for is, which witnesses that
23 you've listed are you planning to call to impeach anything
24 that is presented on this issue by the plaintiffs, and if
25 you're planning on calling any as to start a new substantive

1 issue by the defendants when you don't have any cross-claims
2 or anything like that?

3 MR. ISMAIL: So the testimony of Ms. Jakob and
4 Mr. Matukaitis.

5 THE COURT: They are the plaintiffs witnesses?

6 MR. ISMAIL: They are Merck's witnesses.

7 THE COURT: I'm sorry.

8 MR. ISMAIL: I think part of that confusion arises
9 from the following. Ms. Jakob is a witness for Merck, and
10 Judge Miller has ruled that we should bring Ms. Jakob in
11 plaintiffs' case in chief so they can ask her first. So
12 it's our witness but she is appearing in the plaintiffs'
13 case in chief.

14 THE COURT: If they choose to call her.

15 MR. ISMAIL: They told us they do intend to call
16 her. In fact, I think she is the first or second witness in
17 the trial. And so Ms. Jakob was the in-house counsel at
18 Merck who was responsible for the Glenmark litigation and
19 the *Mylan* litigation. And her factual testimony would, I
20 think, bear on both as matters of impeachment to the
21 plaintiffs' theory of the case and also be supportive of
22 Merck's theory of the case.

23 THE COURT: But if they call her, then you would be
24 calling her to impeach her?

25 MR. ISMAIL: No, sorry. If the plaintiffs call

1 her, they will conduct their examination, and then we will
2 conduct our examination of Ms. Jakob, and there has already
3 been a ruling, in fact, an agreement with plaintiffs that
4 the examination by Merck of Ms. Jakob can go beyond the
5 scope of the subject matter that plaintiffs examine her on.

6 THE COURT: I haven't seen an agreement.

7 MR. ISMAIL: We can tender that to the Court. It
8 was in the context of, at the pretrial conference, and we
9 are happy to provide that to the Court.

10 THE COURT: I'm not understanding how you all are
11 calling witnesses. I mean, why would they be calling a
12 witness in their case in chief that's basically your
13 witness, unless they're calling her as an adverse witness?

14 MR. ISMAIL: They are calling her as an adverse
15 witness.

16 THE COURT: In their case in chief?

17 MR. ISMAIL: Correct. We did oppose this
18 procedure. We were ordered to bring Ms. Jakob in
19 plaintiffs' case in chief over objection, and we are
20 complying with that order.

21 THE COURT: But there is still an objection?

22 MR. ISMAIL: There is.

23 THE COURT: All right.

24 MR. ISMAIL: So Ms. Jakob, I believe, would fall in
25 both categories to Your Honor's question.

1 THE COURT: I understand.

2 MR. ISMAIL: As would Mr. Matukaitis. You've heard
3 from Mr. Armitage, who will be offered affirmatively on the
4 question of what a reasonable and competent patent lawyer
5 would advise.

6 THE COURT: That would be impeachment. You can't
7 offer that unless you're impeaching something that has been
8 presented.

9 MR. ISMAIL: Yes.

10 THE COURT: Depending upon my ruling. In other
11 words, Mr. Armitage would be in defense of what Dr. Hrubiec
12 testifies to?

13 MR. ISMAIL: That does include part of the subject
14 matter of Mr. Armitage.

15 THE COURT: Don't count on just being able to
16 launch off into whatever you want to launch off in because
17 there are rules that set the contours of what can be
18 presented. In other words, if the issue isn't there, you
19 can't present evidence on it.

20 MR. ISMAIL: Yes. And there are -- Mr. Armitage
21 has a very long report that's part of those binders that are
22 before the Court. So there are other subject matters that
23 Mr. Armitage does give opinions on that have not been
24 challenged by plaintiffs and -- but we take the Court's
25 point.

1 THE COURT: The report doesn't come in.

2 MR. ISMAIL: Of course. Of course. I'm just
3 talking about the disclosure of the opinions. But going
4 back to your question, Your Honor, Mr. Armitage does offer
5 opinions for which *Mylan* would be, we believe, of relevance
6 and -- according to reference in support of opinions he
7 wants to offer that are similar to what you heard today,
8 which is what a reasonable and competent patent lawyer would
9 advise his or her client regarding the prospects of Glenmark
10 succeeding on this inventorship challenge.

11 In addition to that, I believe there will be
12 reference to the *Mylan* litigation by Dr. Addanki.

13 THE COURT: You can pass that.

14 MR. ISMAIL: So Dr. Addanki makes reference to
15 *Mylan* litigation, and if you recall from Judge Miller's
16 articulation of the relevance of *Mylan*, in part relates to
17 the procompetitive aspects of the settlement agreement in
18 toto. Dr. Addanki is an expert who addresses that issue and
19 makes references therein. Dr. Burnett, whom you've heard
20 referenced several times today as a joint inventor of the
21 patents at issue, he testified in the underlying patent
22 litigation. He is going to be a witness in this case, will
23 be called by Merck.

24 There are additional counsel -- I'm sorry,
25 additional experts who have been designated on issues of

1 patents, Mr. Figg and Ms. Linck, who's opinions, depending
2 on what the Court allows and what issues the Court deems to
3 be fair game, do reference the *Mylan* procedure -- I'm sorry,
4 the outcome and the reports. I think I've got them all.

5 THE COURT: I'm just trying to get an idea. I'm
6 not going to say because you didn't mention it, if some
7 ruling goes in your favor or if it's appropriate evidence
8 and they have been listed, I'm not going to say because you
9 didn't mention it here. I'm just trying to get some idea.

10 MR. ISMAIL: I appreciate that. I hope that was
11 helpful in at least in qualitatively if not exactly
12 quantitatively.

13 THE COURT: It was helpful.

14 MR. ISMAIL: Thank you.

15 THE COURT: Thank you. The next thing that the
16 Court wants to take up just a couple of administrative
17 matters and comments, and I will be addressing Mr. Noona on
18 the first one.

19 MR. NOONA: Yes, ma'am.

20 THE COURT: Mr. Noona, you've presented on, it's
21 dated 4-10. It came to the Court on 4-12, is forwarded to
22 me on 4-12. *Pro hac vice* admission at this late date, and
23 you're going to have to justify it. I'm not admitting one
24 more attorney into this case.

25 MR. NOONA: Is that Mr. Whittaker, Your Honor?

1 THE COURT: So if he's so important, why haven't
2 you done that before?

3 MR. NOONA: Your Honor, my understanding is
4 Mr. Whittaker will be working on the case. I don't believe
5 he is going to be presenting in the case. But as a
6 precaution, we didn't want him showing up in the court or
7 taking part at all unless he filed a *pro hac vice*. He is
8 part of the Gibson Dunn team. He is in the courtroom today,
9 seated in the corner over here. He is taking a supportive
10 role in the case. But it was out of formality and caution
11 that we filed that, and typically not every lawyer that
12 works on a case files a *pro vac*. He is not, my
13 understanding -- subject to Mr. Liversidge, he is not going
14 to be presenting witnesses or cross-examining or whatnot.

15 THE COURT: I'll take it under advisement, and I'll
16 decide whether I'm going to enter it. It just seems like to
17 me to be excess, but everything is already excessive, so
18 this is like a grain of sand.

19 MR. NOONA: We wanted to be sure rather to find out
20 that there was a problem, Your Honor. That's all.

21 THE COURT: I'll go ahead and enter it and give it
22 to the clerk tonight so that he won't waste his weekend here
23 when he could be out in California.

24 MR. NOONA: Thank you, Your Honor.

25 MR. WHITTAKER: Thank you, Your Honor.

1 THE COURT: You can't get away that quickly,
2 Mr. Noona.

3 MR. NOONA: I'm sorry. It hopeful.

4 THE COURT: Maybe all I have for you at the moment.
5 That's all I had specifically for you.

6 MR. NOONA: Thank you, Your Honor. Happy to appear
7 again anytime.

8 THE COURT: All right. Counsel, each group, in
9 other words, the five sets that have been identified, you
10 have to identify a party representative, and that party
11 representative has to be here throughout the trial. I have
12 not had a designation yet, but the direct purchasers, the
13 retailer plaintiffs, the end payor plaintiffs, you all have
14 to designate, Merck has to designate someone, and Glenmark.
15 It has to be somebody with authority, and we are going to
16 have a case. This case has been pending for five years
17 before this Court, and could go up to five to six weeks, is
18 going to be a party representative. That party
19 representative is going to be here every day.

20 So you need to check with your client and find out
21 who they are going to designate, and you need to let the
22 courtroom deputy know that on Monday by 3:00 so that we will
23 have knowledge of who is going to be here starting on
24 Tuesday.

25 The next matter is any outstanding motion *in*

1 *limines* that have not been ruled upon by the Court may not
2 be mentioned in opening statement. I am going to endeavor
3 to get rulings out, but if it hasn't been ruled on, you
4 cannot mention it. Opening statements are by law, they are
5 not evidence. They are opening statements. They can be
6 restricted, they can be limited, and the jury is told it's
7 just an attorney's way of giving you some idea of what this
8 case is about. They are told repeatedly it is not evidence,
9 and you may not argue in opening statement, and you may only
10 make an opening statement, and you've got your restricted
11 time.

12 If a Court hasn't ruled upon an issue, and it's
13 outstanding, don't mention it, because I will call you down
14 in front of the jury. I will tell you that you are going
15 past the Court rules, if it is something that the Court has
16 not ruled upon. I would also tell you that a motion *in*
17 *limine* is exactly that, to limit the evidence. There is a
18 ruling required on it before the evidence comes before the
19 jury, and as I tried to make clear earlier today, what I was
20 saying was I certainly wasn't going to let evidence come
21 before the jury that I hadn't completed a motion *in limine*
22 ruling on, and that's all that was about. That is not
23 mentioned in opening statements, doesn't mean it can't be
24 evidence in the case. Juries are told this is just a
25 summary, this is just to get you started, and they're told

1 in preliminary instructions, and they are told in their
2 final instructions, that opening statements are not
3 evidence, closing arguments are not evidence, but closing
4 argument is the opportunity for the attorneys to vigorously
5 try to convince you that they are correct based upon the
6 evidence in the case.

7 So if the Court hasn't made a ruling, you should go
8 through, let's see, 44 total, as I have the motions *in*
9 *limine*, I could be wrong, but my last count was 20 from the
10 plaintiffs and 24 from the defendants for a total of 45 that
11 have been ruled upon. I have a short list of what has not
12 been ruled upon, but you know those. It's only a few. So I
13 would tell you that now.

14 The next bit of advice I have is that you spend
15 your time working on, if you can, some type of stipulation
16 in regard to this *Mylan* litigation, and I would also
17 suggest, and I have mentioned this to Judge Miller,
18 technically you still haven't finished your final pretrial
19 conference, shocking to the Court, because part of getting a
20 case ready for trial, this case has been pending before the
21 Court five years in June, I believe it's June. I know it
22 was June of 2018. So it will be five years in June. You're
23 supposed to have your deposition designations made and ruled
24 upon before trial, and you all are still at that. So I
25 would suggest that you use Monday, that you now have, to do

1 some productive things for trial, such as completing
2 deposition designations, working on some stipulations, and
3 thinking now about how you present a case to a jury, not
4 just arguing and bickering between attorneys in front of the
5 Court, but how you present a case to a jury. You all are
6 experienced.

7 The jury has to understand the forest. They don't
8 care about all the trees. They want to know the forest, and
9 you all have got to think about, this is not a bench trial
10 where a judge can sort through those kinds of things. This
11 is a jury trial. It is your job. It's not the Court's job,
12 it's your job to educate them. I think I made the analogy
13 before it's like assume you are a freshman in college, and
14 you're starting a foreign language course, and you've never
15 spoken that language and don't know a thing about it.

16 It's the job of that teacher to bring you in and
17 start you on that language course, and by the end of the
18 semester, you understand it, at least to make a passing
19 grade. So that's what you're dealing with here. You are
20 not dealing with patent experts, you're not dealing with
21 antitrust experts, and it's my job to instruct them on the
22 law in the end of the case when they've heard the evidence
23 and for them to apply the evidence they have to the law to
24 make their finding of fact. You all are the ones who have
25 to make that possible. Juries are very smart and very savvy

1 in my experience through the years. They favor parties who
2 make their cases clear, not who try to obfuscate and stir it
3 all up and take their time in doing it. So those are just a
4 few words that I wanted to say to you in terms of
5 administrative matters.

6 The final is, I'll give it, if you want it, each of
7 you, Mr. Sobol, Mr. Liversidge. I have trouble with your
8 name. I'm sorry.

9 MR. LIVERSIDGE: Liversidge.

10 THE COURT: Mr. Liversidge and Mr. Ismail, one, not
11 both, 10 to 15 minutes for any wrap-up, you can have it. If
12 you don't, that's fine, too.

13 Mr. Sobol, is there anything further you want to
14 say?

15 MR. SOBOL: I think the plaintiffs are content,
16 Your Honor.

17 THE COURT: All right.

18 MR. LIVERSIDGE: Same for us, Your Honor. Nothing
19 further.

20 THE COURT: Thank you. Counsel, I wish you, I
21 wouldn't say happy, but I wish you a safe weekend, and so I
22 will see you next at 11:00 a.m. on Tuesday morning. So the
23 Court stands in recess until then.

24 (Hearing adjourned at 5:27 p.m.)
25

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

CERTIFICATION

I certify that the foregoing is a correct transcript
from the record of proceedings in the above-entitled matter.

X _____ /s/ _____ X

Jody A. Stewart

X _____ 4-17-2023 _____ X

Date

JODY A. STEWART, Official Court Reporter